the State Government shall provide information of the advertisements to the Central Government on quarterly basis and also as and when sought by the Central Government.

- (15) The State Licensing Authority may suspend or cancel the license of the manufacturer of the Ayurvedic, Siddha or Unani drug as per the provisions of Rule 159, in case the directions given by the said authority is not complied.
- (16) The Central Government shall, in the public interest, prohibit any advertisement of the Ayurvedic, Siddha or Unani drugs, by notification in the Official Gazette.]

SCHEDULE A
FORM 1
(See rule 4)
MEMORANDUM TO THE CENTRAL DRUGS LABORATORY
Serial Number
From
Fromसत्यमेव जयते
I send herewith, under the provisions of section 25(4) of the Drugs and
Cosmetics Act, 1940, sample(s) of a drug purporting to
be for test or analysis and request that a report of the
result of the test or analysis may be supplied to this Court.
2. The distinguishing number on the packet is
3.Particulars of offence alleged
4. Matter on which opinion is required
5. A fee of Rshas been deposited in Court.
Date Magistrate

¹[Form 1A

(See rule 163C)

²[Pharmacopoeia Commission for Indian Medicine and Homoeopathy, Ghaziabad (Uttar Pradesh)]

From
(Full name, Designation and Postal address of the sender)
Serial No
To the Director,
Pharmacopoeial Laboratory for Indian Medicine,
I send herewith under the provisions of section 11 (2)/section 25(4) and section 33H of the Drugs and Cosmetics Act, 1940, sample(s) of a drug purporting to be
Date
Magistrate/Authorized Signatory.]

FORM 2

(See rule 6)

CERTIFICATE OF TEST OR ANALYSIS BY THE CENTRAL DRUGS LABORATORY

Certified that the samples, bearing numberpurporti	ing
to be a sample ofw	ith
memorandum Nofro	om
has been tested/analysed and that the result of su	ıch
test/analysis is as stated below.	
2. The condition of the seals on the packet on receipt was as follows:—	
*3. In the opinion of the undersigned the sample is of standard quality is not	
standard quality as defined in the Drugs and Cosmetics Act, 1940, and rule thereunder for the reasons given below:	les
thereunder for the reasons given below: Direct	
Date Central Drugs Laboratory or other Authorised Officer	
CDSCO CDSCO	
Details of results of test or analysis with protocols of test applied	
Details of results of test or analysis with protocols of test applied OF HEALTH, GOVERNMENT Direct	tor
DateCentral Drugs Laboratory or other Authorised Officer	
* If opinion is required on any other matter, the paragraph should be suitab	oly

amended.

¹[FORM 2A

(See rule 163E)

CERTIFICATE OF TEST OR ANALYSIS FROM THE ²¹²[PHARMACOPOEIA COMMISSION FOR INDIAN MEDICINE AND HOMOEOPATHY] OR GOVERNMENT ANALYST

Certified that the samples, b	earing number	purporting to be
a sample of	received	onwith
memorandum		No
datedfr	om	has been tested/ analysed
and that the result of such te	st/analysis is as stated	below.
2. The condition of the seals	s on the packet on recei	pt was as follows:—
*3. In the opinion of the	undersigned the samp	ole is of standard quality as
defined in the Drugs and	Cosmetics Act, 1940,	or rules thereunder for the
reasons given below.	Or	or rules thereunder for the
In the opinion of the und	ersigned the sample i	sonot of standard quality as
		or rules thereunder for the
reasons given below. "Note.—*delete whichever	is not applicable "when	
(S	Signature of the Analys	t Person-in-Charge of testing)
Date		
Place	Name & Designation	& Seal
	Name & Address of	the Laboratory]

¹[***]

²[FORM 8

(See rule 24)

APPLICATION FOR LICENCE TO IMPORT DRUGS (EXCLUDING THOSE SPECIFIED IN SCHEDULE X) TO THE DRUGS AND COSMETICS RULES, 1945

I/we*(full address with telephone number,
fax number and e-mail address) hereby apply for a licence to import drugs
specified below manufactured by M/s(full address,
with telephone number, fax, and e-mail no.)
2. Names of the drugs to be imported:
(1)
(2)
(3)
3. I/we*, enclose herewith an undertaking in
3. I/we*,
Form 9 datedsigned by the manufacturer as required by rule 24 of the Drugs Rules, 1945
4. I/we,, enclose herewith a copy of
Registration Certificate concerning the drugs to be imported in India, issued
under Form 41 of the rules, wide Registration Certificate No Dated issued
Dated issued through
M/s(name and full address)
valid upto सुरुप्ते ज्याते
5. I/we*, hold a valid wholesale licence
for sale or distribution of drugs or valid licence to manufacture drugs, under the
provisions of the Act and rules made thereunder. A copy of the said licence is
enclosed.
6. A fee ofhas been credited to Government under the Head of
Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and
Fines." under the Drugs Rules, 1945—Central vide Challan No
dated (attached in original)
Signature
Name
Designation
Seal/Stamp of Manufacturer's agent in India
Place:
Date:
* Delete whichever is not applicable]

¹[FORM 8A

(See rule 24)

APPLICATION FOR LICENCE TO IMPORT DRUGS SPECIFIED IN SCHEDULE X TO THE DRUGS AND COSMETICS RULES, 1945

I/we*,, (full address with telephone number,
fax number and e-mail address) hereby apply for a licence to import drugs
specified below manufactured by M/s(full address with
telephone no, fax and e- mail no.)
2. Names of the drugs to be imported
(1)
(2)
(3)
3. I/we*,, enclose herewith an undertaking in Form 9 dated
signed by the manufacturer as required by rule 24 of Drugs and
Rules, 1945.
Rules, 1945. 4. I/we*,
Registration Certificate concerning the drugs to be imported in India issued
under Form 41 of the rules, vide Registration Certificate No
Dated issued through M/scpsco
addressvalid upto
address
licence for sale or distribution of drugs or licence to manufacture drugs, under
the provisions of the Act and rules made thereunder. A copy of the said licence
is enclosed.
6. A fee ofhas been credited to Government under the Head
of Account "0210—Medical and Public Health, 04—Public Health, 104—Fees
and Fines" under the Drugs Rules, 1945—Central vide Challan
No dated (attached in original).
Signatures
Name
Designation
Seal/Stamp of Manufacturer's agent in India
Place
Date
* Delete whichever is not applicable.]

FORM 9

(See rule 24)

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR AN IMPORT LICENCE

	Designation
Seal/Stamp of manufacturer	or on behalf of the manufacturer

³[FORM 10

(See rules 23 and 27)

LICENCE TO IMPORT DRUGS (EXCLUDING THOSE SPECIFIED IN SCHEDULE X) TO THE DRUGS AND COSMETICS RULES, 1945

Licence Numbe	r		•••••	Date	• • • • • • • • • • • • • • • • • • • •	••
1	(name	and	Full	address	of	the
importer)	• • • • • • • • • • • • • • • • • • • •	is	hereby li	censed to imp	ort into	India
during the period	by M/s			(nai	me and	full
address) and ar	ly other drug	s manurac	tureany t	ne said manufa	acturer as	s may
address) and ar from time to tim 2. This licence	ne be endorsed shall be in for	l on this li	cence.	ORGANO.	1	unless
it is sooner susp	ended or cand	elled und	er the said 1	rules.		
3. Names of d	rugs to be imp	orted:	CDS	CO		
Place Date	MINIS			MOIA		
Date	<i>₹</i>	० सत्यमे	व जयते 🦼	KOK OK		
		HEALTH.	GOVERNME	LICENSING	AUTHO	RITY
		-,			Seal /S	Stamp

Conditions of Licence

- 1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
- 2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.

- 3. The licencee shall be responsible for the business activities of the manufacturer in India alongwith the registration holder and his authorised agent.
- 4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

¹[FORM 10A

(See rules 23 and 27)

LICENCE TO IMPORT DRUGS SPECIFIED IN SCHEDULE X TO THE DRUGS AND COSMETICS RULES, 1945

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence produced, whenever required.

Seal/Stamp

- 2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
- 3. The licencee shall be responsible for the business activities of the manufacturer in India alongwith the registration holder and his authorised agent.
- 4. The licencee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

FORM 11 (See rule 33)

LICENCE TO IMPORT DRUGS FOR THE PURPOSES OF EXAMINATION, TEST OR ANALYSIS

1	of	सत्यमव ज	ायत	asis he	ereby li	censed	to impor	t
from	the drugs spe	cified be	low fo	r the p	purpose	s of ex	amination	,
test or analys	is at	or in	such	other	places	as the	e licensing	5
authority may	from time to time a	uthorise.						

- 2. This licence is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.
- 3. This licence shall, unless previously suspended or revoked, be in force for a period of '[three years] from the date specified below:

Names of drugs	Quantity which may be imported

Date		LICEN	SING AUTHORITY
			Seal/Stamp
	Names of drugs	Quantity which may be im	ported
Place		·	
Date			SING AUTHORITY
	es"	TANDARD CONTROL	Seal/Stamp
	OF GRIGS	onditions of Licence	
1. The 1	licence shattosh	e displayed in the off	ice of the Medical

- Superintendent of Government Hospital/Head of Institution of Autonomous Medical Institution.
- 2. The licencee shall store the drugs imported under this licence under proper storage conditions.
- 3. The drugs under this licence shall be exclusively used for the treatment of patients, and a record shall be maintained in this regard, by a registered pharmacist giving the full name(s) and address(es) of the patients, diagnosis, dosage schedule, total quantity of drugs imported and issued, and shall be countersigned by the Medical Superintendent of the Government Hospital of Head of the Autonomous Medical Institution which shall be produced, on demand by an Inspector appointed under the Act.]

FORM 12 (*See* rule 34)

APPLICATION FOR LICENCE TO IMPORT DRUGS FOR PURPOSE OF EXAMINATION, TEST OR ANALYSIS

1	,	resident	of .	by
occupation	. hereby appl	y for a licenc	e to import t	the drugs specified
below for the purpose	of examinat	ion, test or a	nalysis at	from
and	I undertake	to comply with	th the condi	tions applicable to
the licence.				
¹ [²¹⁴ [A fee of rupe	es	has	been credit	ed to Government
under the Head of Acco				
104-Fees and Fines un				•
Challan No da	_			
Names of drugs Quant	ity which mo	y be imported	d	
	APUGS (S)		Ope	
	2 Call		32	
DL	NI RA		ZAT TA	
Place	<u></u>		ICENICINIC	AUTHODITY
Date	·····cdsco	CDS	ICENSING	AUTHORITY
	MINISTRA	ORM 12A	MONA	
		Gusecond pro		
APPLICATION FOR	12	IH. GOVE		
QUANTI	TIES OF DE	RUGS FOR P	ERSONAL	USE
1	resident		(ofby
occupation	hereby	y apply for a	a permit to	import the drugs
specified below for per	rsonal use fro	om I attach a	prescription	from a registered
medical practitioner in	regard to the	need for the s	aid drugs.	
Names of drugs	Quantity wh	ich may be im	ported	
1				
Date		Signatu	ıre]

²[FORM 12AA

(See rule 34A)

APPLICATION FOR LICENCE TO IMPORT SMALL QUANTITIES OF NEW DRUGS BY A GOVERNMENT HOSPITAL OR AUTONOMOUS MEDICAL INSTITUTION FOR THE TREATMENT OF PATIENTS

I, (name) (and	d designation) of
(name	e of the Hospital/Autonomous Medical
Institution)	hereby apply for a licence to import
small quantities of new drugs specif	fied below for the purpose of treatment of
patients for the disease	(name of the disease)
at(name and place of	of the hospital) and I undertake to comply
with the conditions applicable to the	e licence and other provisions of the Drugs
TAND	es made thereunder, from time to time.
1. A fee of rupees	has been credited to Government under
the Head of Account "0210-Medical	and Public Health, 04-Medical and Public
	the Drugs and Cosmetics Rules, 1945—
Central vide Challan No	., dated, (attached in
original).	CDSCO
2. Name of new drug to be imported Names of drugs Quantity which may	The state of the s
Names of drugs Quantity which may	प्रमेव जयते he imported
Zumung Zumung MEAL	TH, GOVERNA
Place	
Date	Signature
	Name
	Seal/Stamp.
CER	TIFICATE
Certified that the drugs specified abo	ove for import are urgently required for the
	and that the said
drug(s) is/ are not available in India.	
	a.
	Signature

	Medical Institution
	Seal/Stamp
Place	
Date]	
¹ [FORM 12B	
(See rule 36, second pro	ovico)
PERMIT FOR THE IMPORT OF SMALL	
FOR PERSONAL U	
FOR I ERSONAL C) 3 L
is hereby permitted to in	nport from the
drugs specified below for personal use.	
2. This permit is subject to the conditions pr	rescribed in the Rules under the
Drugs and Cosmetics Act, 1940.	2
	ROM
3. This permit shall, unless previously susp	pended or revoked, be in force
²¹⁵ [till such time as the patient requires the dru	ng as per the prescription of a
registered medical practitioner and the permit	holder shall submit details of
drugs imported and utilised to the licensing auth	ority on yearly basis] from the
date specified below.	Man
	A SECOND
Names of drugs Quantity which may be imported	
ALTH, GOVE	
I II	
Date	Licensing Authority.]
FORM 13	
(See rule 46)	
CERTIFICATE OF TEST OR ANALYS	SIS BY GOVERNMENT
ANALYST UNDER SECTION 25(1) OF THE	DRUGS AND COSMETICS
ACT, 1940	
1. Name of Inspector from whom received	
2. Serial No. and date of Inspector's memorar	ndum

Medical Superintendent of the Government Hospital/ Head of Autonomous

² [In the opinion of the undersigned the sample referred to above is of standard/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the reasons given below:]
Date
FORM 14A
(See rule 47)
APPLICATION FROM A PURCHASER FOR TEST OR ANALYSIS OF
A DRUG UNDER SECTION 26 OF THE DRUGS AND COSMETICS
ACT, 1940
1. Full name and address of the applicant
2. Occupation
3. Name of drug purporting to be contained in the sample
4. Name and full address of the pharmacy or concern where the drug was
purchased
5. Date on which purchased
5. Date on which purchased
6. Reasons why the drug is being submitted for test or analysis
³ [7. A fee of rupeesvide Schedule B to the Drugs Rules, 1945,
has been credited to Government under the head of account "080-Medical-
Miscellaneous-Fees under the Drugs and Cosmetics Rules, 1945—
Central/State"— <i>vide</i> treasury receipt attached.]
I hereby declare that the drug being submitted for test was purchased by or for me. I further declare that the sample of the drug being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way to reduce its potency.
DateSigned

FORM 14B 228, 238, 239

(See rule 47)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 26 OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of person from whom sample received	
2. Date of receipt	
3. Name of drug purporting to be contained in the sample	
4. Opinion of the Government Analyst—The sample referred not of standard quality as defined in the Drugs and Cosmetics arules thereunder. Date	d to above is/is Act, 1940, and
Date	
ORDER UNDER SECTION 22(1) (C) OF THE DRUG	
COSMETICS ACT, 1940 REQUIRING A PERSON NOT T	O DISPOSE
OF STOCK IN HIS POSSESSION	
Whereas, I have reason to believe that the stocks of drugs/21	¹⁷ [***] in your
possession detailed below contravene the provisions of section 1	
and Cosmetics Act, 1940;	C
Now, therefore, I hereby require you under clause (c) of subsection 22 of the said Act, not to dispose of the said stock ofdays from the date of this order.	
DateInspector	
Details of stock of	of drugs/ 2 [***].
Date In	nspector]

³[FORM 16

(See rules 55 and 145B)

RECEIPT FOR STOCK OF DRUGS 218 [***] FOR RECORD, REGISTER DOCUMENT OR MATERIAL OBJECT SEIZED UNDER SECTION 22(1)(C) OR (CC) OF THE DRUGS AND COSMETICS ACT, 1940

The stock of drugs	or ² [***] or records, registers, documents or r	naterial
objects, detailed below	v has/have this day been seized by me und	der the
provisions of clause (c)	or clause (cc) of sub-section (1) of section 22	of the
Drugs and $^2[***]$ A	ct, 1940 (23 of 1940), from the premi	ses of
sit	uated at	
Date	Inspector	
2-	STANDARD CONTRO	
Details of drugs, ² [***], records, registers, documents or material	objects
seized.		
Data	Inspector*** ***] records, registers, documents or material Inspector	1
Date	mspector	· J
C	cDSCO ¹ [FORM 17cDSCO	
	(See rules 56 and 145A)	
INTIMATION TO	(See rules 56 and 145A) प्र PERSON FROM WHOM SAMPLE IS TAK सत्यमेव जयते अस्तिमा, GOVERNMENT	EN
	क्र- सत्यमेव जयते ४०	
То	OF HEALTH ON ERNMEN	
	TICIH, GOVES	
••••••		
I have this day taken	from the premises of	situated
-	the drugs $\frac{219}{219}$ [***] specified below for the pur	
test or analysis.		•
•		
Date	Inspector	
	Details of sample taken	
Date	Inspector	

3[FORM 17A

(See rules 56A and 145AA)

RECEIPT FOR SAMPLES OF DRUGS ²²⁰[***] TAKEN WHERE FAIR PRICE TENDERED THEREOF UNDER SUB-SECTION (1) OF SECTION 23 OF THE DRUGS AND COSMETICS ACT, 1940 IS REFUSED

To
Whereas I, thisday of ²²¹ [20], have taken from the premises of situated at samples of drugs/cosmetics as specified below:—
And whereas I had offered to pay you rupeesas the fair price of the samples of drugs/cosmetics taken:
And whereas I had offered to pay you rupeesas the fair price of
the samples of drugs/cosmetics taken:
And whereas, you have refused to accept the fair price tendered thereof;
Now, therefore, I give you this receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.
Date
FORM 18
(See rule 57)
MEMORANDUM TO GOVERNMENT ANALYST
Serial No. of Memorandum
From

The Government Analyst

To

The portion of sample/container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of section 23 of the Drugs and ²[***] Act, 1940.

which it purports to contain—
DateInspector
¹ [FORM 18A
[See rule 163(1)]
MEMORANDUM TO GOVERNMENT ANALYST
Serial No
From
To
The portion of sample/container described below is sent herewith for test or analysis under the provision of section 33H of the Drugs and Cosmetics Act, 1940. CDSCO CDSCO CDSCO The portion of sample/container has been marked by me with the following mark. Details of portion of sample or container with name of ingredients from which it is claimed to be made.
DateInspector
² [FORM 19
[See rule 59(2)]
APPLICATION FOR GRANT ³ [***] OF A ²²² [LICENCE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULE X

1. I/We,, hereby apply for licence to sell by wholesale/retail drugs specified in Schedules C and C(l) excluding those specified in Schedule X* and /or drugs other than those specified in Schedules C, C(l) and X to the Drugs and

The portion of sample/container has been marked by me with the following mark. Details of portion of sample or container with name of ⁵[drug/²[***]]

Cosmetics Rules, 1945* and also to operate a pharmacy on the premises situated at
2. ! The sale and dispensing of drugs will be made under the person supervision of the qualified persons namely:—
(Qualification).
3. Categories of drugs to be sold.
4. # Particulars for special storage accommodation.
5. A fee of rupeeshas been credited to the Government account under the head of account
DateSignature
* Delete whichever is not applicable ! To be deleted if drugs will be sold only by wholesale # Required only if products requiring special storage are to be sold. **CDSCFORM 19ACDSCO** [See rule 59(2)] **APPLICATION FOR THE GRANT** [***] OF A RESTRICTED **223[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] DRUGS BY RETAIL BY **224* [***I DEALERS WHO DO NOT ENGAGE THE SERVICE OF QUALIFIED PERSON
1. I/We,
or (ii) Drugs specified in ^s [Schedule C(l)] on the premises situated at/ Drugs specified in ²²⁶ [Schedule C(l)] as vendor in the area
2. Sales shall be restricted to such drugs as can be sold without the supervision of a qualified person under the Drugs and Cosmetics Rules.
3. Names or classes of drugs proposed to be sold

!5. The drugs for sale will be purchased from the following dealers and such other dealers as may be endorsed on the licence by the licensing authority from time to time.
Name of the dealersLicence No
6. A fee of rupees ³ [***]/ [#] twenty has been credited to Government under the head of account
DateSignature
* Delete if not required. ! Applies only to an itinerant vendor. ARD COVIDED # Rupees five for itinerant vendors and applicants from a village or town having a population of 5,000 or less, and rupees twenty for other restricted licence. **FORM** 19AA ***** OF A 2 LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE BY WHOLESALE, OR DISTRIBUTE DRUGS FROM A MOTOR VEHICLE 1. I/We,
2. Categories of drugs to be sold/distributed
3. A fee of rupeeshas been credited to Government under the head of account
*4. Particulars of the storage accommodation for the storage of drugs specified in Schedules C and C(l) on the vehicle referred to above.
Date]

*4. Particulars of the storage accommodation for the storage of Schedule C(l)

drugs on the premises referred to above.

* Delete if not required.

FORM 19B

(See rule 67A)

APPLICATION FOR ³[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES

1. I/We,
*2. The sale and dispensing of Homoeopathic medicines shall be made under the person supervision of the following competent person-in-charge.
Name
3. A fee of rupees
* Delete whichever is not applicable. CDSCO CDSCO CDSCO CDSCO CDSCO CDSCO CSECTURE 59(2) CDSCO CD
APPLICATION FOR GRANT [LICENCE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] DRUGS SPECIFIED IN SCHEDULE X
1. I/We,hereby apply for a licence to sell by "*wholesale/retail drugs specified in Schedule X to the Drugs and Cosmetics Rules, 1945. We operate a pharmacy on the premises, situated at
!2. The sale and dispensing of drugs will be made under the personal supervision of the qualified persons mentioned below:
(Name) (Qualification)
(Name) (Qualification)

3. Name of drugs to be sold.
4. #Particulars of storage accommodation.
5. A fee of rupeeshas been credited to Government account under the head of account
Date
* Delete whichever is not applicable.
! To be deleted if drugs will be sold only by wholesale.
Required only if products requiring special storage are to be sold.]
FORM 20
[See rule 61(1)] ¹ [LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE,
OR DISTRIBUTE] DRUGS BY RETAIL OTHER THAN THOSE
SPECIFIED IN HSCHEDULES C, C(I) AND X]
1
exhibit or offer for sale or distributed by retail drugs other than those specified
in ² [Schedules C, C(1) and X] of the Drugs and Cosmetics Rules. 1945, * and to
operate a pharmacy on the premises situated atsubject to the
conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder ALTH, GOVERNMENT
³ [2. The licence unless sooner suspended or cancelled, shall remain valid
perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years or
as needed as per risk based approach.]
3. Name(s) of qualified person(s)-in-charge
4. Categories of drugs
Name of the dealerLicence NoLicence
Date Licence No
Licensing Authority
* Delete if not applicable.

Conditions of Licence

- 1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
- 2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
- 3. The licensee shall report to the licensing authority any change in the qualified staff incharge within one month or such change.
- 4. No drug shall be sold unless such drug is purchased under case or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- 5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

FORM 20A

[See rule 61(1)]

RESTRICTED ^LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] DRUGS BY RETAIL OTHER THAN THOSE SPECIFIED IN ²²⁹[SCHEDULE C, C(I) AND X] FOR ²³⁰[***] DEALERS WHO DO NOT ENGAGE THE SERVICES OF A QUALIFIED PERSON

	1.,						is her	eby ¹[licensed to	sell, stoc	k or e	xhibit
or	off	er	for	sale,	or	distribute	on	the	premises	situated	at	³ [***]
	• • • • • • •			t	he fo	llowing d	lrugs t	eing	drugs other	r than thos	se spe	cified
in	² [Sc]	hed	ules	C, C(1)) and	X] of the	e Drug	gs and	Cosmetics	Rules, 19	945 s	ubject
to	the	coı	nditio	ons sp	ecifie	ed below	and 1	to the	provision	s of the	Drug	s and
Co	sme	tics	Act,	1940 a	and t	ne rules m	ade th	ereun	der.			

⁴[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the

provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

3. Th	e licensee	can d	eal or	ıly in	such	drugs	as	can	be	sold	withou	ıt t	the
supervisi	on of a "qı	ualified	perso	n" un	der the	e Drugs	ano	d Co	sme	etics I	Rules, 1	194	15.

⁵ [***]						
Date	Licensing Authority					
Conditions of Licence						

- 1. The licence shall be displayed in a prominent place in a part of the premises open to the public ${}^{3}[***]$
- 2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
- 3. No drugs shall be sold unless such drug is purchased under a case or credit memo from duly licensed dealer or a duly licensed manufacturer.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

FORM 20B

[See rule 61(1)]

HLICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY WHOLESALE, DRUGS OTHER THAN THOSE SPECIFIED IN ²[SCHEDULES C, C(I) AND X]

1,...... is hereby ¹[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale drugs other than those specified in ²[Schedules C, C(1) and X] on the premises situated at......subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940, and the rules thereunder.

⁴[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

Conditions of Licence

- 1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
- 2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.
- ¹[3. (i) No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- (ii) No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug. Provided that the condition shall not apply to the sale of any drug to—
- (a) an officer or authority purchasing on behalf of Government, or
- (b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or]

EALTH, GOVERN

²[(c) a manufacturer of beverages, confectionary biscuits and other non-medicinal products, where such drugs are required for processing these products;]

5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

⁴[FORM 20BB

(See rule 62D)

⁵[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE BY WHOLESALE, OR DISTRIBUTE] DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULE C AND SCHEDULE C(I) TO DRUGS AND COSMETICS RULES, 1945, FROM A MOTOR VEHICLE

1.,		, is hereby	⁵ [license	d to sell,	stock or
exhibit or offer	for sale by who	lesale, or dist	ribute] dru	gs other th	an those
specified in Scheo	dule C and Scheo	dule C(1) from	the vehicle	bearing reg	gistration
Noass	signed under M	otor Vehicle	es Act, 19	39, subject	t to the
conditions specifi	ied below and to	the provision	s of the D	rugs and C	osmetics
Act, 1940 and the	Rules made ther	eunder.			
612 The ligan	oo unlaga soonoy	AND ARD COM.	. aanaallad	chall rame	sin volid

⁶[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

3. Categories of drugsCDSCO	
DateLicence No	••••
सत्यमेव जयते हुन	
MEALTH Licensing Authority	•••••

Conditions of Licence

- 1. This licence shall be displayed in a prominent place on the vehicle.
- 2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the time being in force.
- 3. (i) No drug shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- (ii) No sale wholesale or distribution of any drug shall be made to a person not holding the requisite licence to sell, stock, or exhibit for sale or distribute the drug:

Provided that the condition shall not apply to the sale of any drug to—

(a) an officer or authority purchasing on behalf of Government, or

- (b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or
- (c) a manufacturer of beverages, confectionary biscuits and other non-medicinal products, where such drugs are required for processing these products;
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.
- 5. The licensee shall inform the licensing authority in writing in the event of any change in ownership of the vehicle specified in this licence within seven days of such change.]

[FORM 20C (See rule 67C) ²[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES BY RETAIL

2	Th_{Δ}	licanca	chall	ha	in	force from	to
/		110 6110 6	SHAH	11-		1010-110111	1()

2	NT C.1		. 1
3.	Name of th	e competent	person-in-charge.
J.	Tallic of the	c competent	person in charge.

Б	T
Date	Licensing Authority
Date	.Dicclising radiontry

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

- 2. The licensee shall comply with the provisions applicable to Homoeopathic medicine under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder for the time being in force.
- 3. The licence shall report to the Licencing Authority any change in the competent staff within one month of such change.]
- ¹[4. This licence authorises the sale of Homoeopathic medicines made from one earlier potency up to a quantity of 30 ml. at a time.]
- ²[5. Where any change in the constitution of the firm takes place, a licensee shall inform the licensing authority in writing about the same and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

³[FORM 20D (See rule 67C)

"[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOFOPATHIC MEDICINES BY WHOLESALE

1 ,	<u> </u>	, is hereb	y "[licensed	to sell, sto	ck or exhibit
or offer for sale	e, or distribute] by wholesa	e Homoeop	athic medi	cines on the
premises situate	ed at	subject to th	e conditions	specified b	below and to
the provisions	of the Drugs	and Cosmetic	es Act, 1940), and the	rules made
thereunder.					
O. T 1'		1	C		4 -

2.The	licence	shall	be	in	force	fromto
•••••	•••••	••••				
Date		••••				

Licensing Authority.....

Conditions of Licence

1. This licence shall be displayed in a prominent place on the premises.

- 2. The licensee shall comply with the provisions as applicable to Homoeopathic medicines under the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the time being in force.
- 3. No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exhibit for sale or distribute the drug. Provided that this condition shall not apply to the sale of any drug to (a) an authority purchasing on behalf of Government, or
- (b) a hospital, medical, educational or research institution or a Homoeopathic medical practitioner for the purpose of supply to his patients.]
- ⁵]4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence and the current licence shall be valid only for a period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

¹[FORM 20E CDSC/See rule 67EE)SCO

CERTIFICATE OF RENEWAL OF 232 [LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] HOMOEOPATHIC MEDICINES

HEALTH, GOVERNM

Number of licence and date of issue.....

Certifie	ed that	licence	No	in	Form	20C/	20D	grant	ed	on
the		to	for	sale of	Homo	eopathic	medi	cines	at	the
premises	situated	l at		has	been	renewed	d for	a	per	boi
from		to	• • • • • • • • • • • • • • • • • • • •		••••					

2.	Name of competent person-in-charge.				
Date		Licensing Authority			

³[FORM 20F

[See rule 61(3)]

LICENCE TO SELL, STOCK OR EXHIBIT FOR SALE OR DISTRIBUTE BY RETAIL DRUGS SPECIFIED IN SCHEDULE X

1is hereby licensed to sell, stock or exhibit
for sale or distribute by retail drugs specified in Schedule X to the Drugs and
Cosmetics Rules, 1945 on the premises situated at
2. Names of drugs.
⁴ [3. The licence unless sooner suspended or cancelled shall remain valid
perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years or
as needed as per risk based approach.] 4. Name(s) of qualified person-in-charge.
5. The licence is subject to the conditions stated below and the provisions
of the Drugs and Cosmetics Act, 1940 and the Rules, made thereunder.
DateLicence No.
DateLicence No
Conditions of Licence

- 1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
- 2. The licensee shall report to the licensing authority any change in the qualified staff-in-charge within one month of such change.
- 3. No drug shall be stocked or sold unless such drug has been purchased under cash/credit memo from a duly licensed dealer or a duly licensed manufacturer.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where

any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

¹[FORM 20G

[See rule 61(3)]

²[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY WHOLESALE DRUGS SPECIFIED IN SCHEDULE X

1, is hereby $\frac{255}{1}$ [licensed to sell, stock or
exhibit or offer for sale, or distribute] by wholesale drugs specified in Schedule
X to the Drugs and Cosmetics Rules, 1945, on the premises situated
at
2. Names of drugs
³ [3. The licence unless sooner suspended or cancelled shall remain valid
perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years of as needed as per risk based approach.
4. This licence is subject to the conditions stated below and the provisions of
the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.
Date Licence No
Licensing Authority
Conditions of Licence

- 1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
- 2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.

- 3. No drug shall be stocked or sold unless such drug has been purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- 4. The licensee shall forward to the licensing authority copies of the invoices of sales made to the retail dealers.
- 5. No sale of any drug by wholesale shall be made to a person not possessing the requisite licence to sell, stock or exhibit for sale or distribute the drugs specified in Schedule X:

Provided that the condition shall not apply to the sale of any drug to—

- (a) an officer or authority purchasing on behalf of Government;
- (b) a hospital, medical, educational of research institution, nursing home, Registered Medical Practitioner for the purpose of supply to its/his patients, or manufacturer holding a licence in Form 25E or 28B to manufacture the drugs containing drugs included in Schedule X.]

⁴[The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence, where any change in the constitution of the firm takes place. The current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

FORM 21

[See rule 61(2)]

^LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY RETAIL DRUGS SPECIFIED IN SCHEDULES C AND C(1) ²³⁴[EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

³ [1	is hereby ² [licensed to sell, stock or exhibit or offer
for sale or distribute] by retail the following categories of drugs specified in
Schedules C and C(l) ² [excluding those specified in Schedule X] to the Drugs
and Cosmetics Rules	, 1945* and to operate a pharmacy on the premises situated

at.....subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.]

- ⁴[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";
 - 3. Name(s) of qualified persons in charge.....

3- 4	~	0 1		
J И	('otagoriae	of drugs	S	
1 4 .	Calegories	or urugs	5	

Consing Authority.....

* Delete if not applicable

Conditions of Licence

- 1. This licence shall be displayed in a prominent place in a part of the premises open to the public.
- 2. The licensee shall report to the licensing authority any change in the qualified staff in charge within one month of the such change.
- 4. If the licensee wants ¹[to sell, stock or exhibit or offer for sale, or distribute] during the currency of the licence, additional categories of drugs listed in Schedules C and C(l) ²[excluding those specified in Schedule X] but not included in this licence, he should apply to the licensing authority for the necessary permission. This licence will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the licence by the licensing authority.
- ⁶[5. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.]
- 6. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where

any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

FORM 21A

[See rule 61(2)]

RESTRICTED '[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY RETAIL DRUGS SPECIFIED IN

²[SCHEDULE C(1)] ²³⁵[EXCLUDING THOSE SPECIFIED IN SCHEDULE X] FOR ²³⁶[***] DEALERS WHO DO NOT ENGAGE THE SERVICES OF A QUALIFIED PERSON

1						
exhibit or offer for sale,	or distribute] by retail	on the p	premises	situated	at
⁴ [***]						
²³⁷ [Schedule C(l)] ³ [exclu	ding those spe	ecified in S	chedule ?	X] to the	Drugs a	ınd
Cosmetics Rules, 194ี s	subject to the	conditions	specifie	d below	and to t	the
provisions of the Drugs ar	nd Cosmetics	Act, 1940, a	nd Rules	thereun	der.	
5ro m 11 3	Parenter College					1. 1

- ⁵[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]
- 3. Particulars of 2 [Schedule C(l)] 3 [excluding those specified in Schedule X] drugs to be sold......

Date..... Licensing Authority

Conditions of Licence

1. This licence shall be displayed in a prominent and conspicuous place in a part of the premises open to the public $\frac{238}{8}$ [***].

- 3. The licensee shall deal only in such drugs as can be sold without the supervision of a "qualified person" as defined in the Explanation to sub-rule (15) of Rule 65 of the Drugs and Cosmetics Rules, 1945.
- 4. No drug shall be sold unless such drug is purchased under cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- '[5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

[See file 61(2)] ²[LICENCE TO SELL, STOCK OR EXHIBIT OR OFFER FOR SALE, OR DISTRIBUTE] BY WHOLESALE DRUGS SPECIFIED IN SCHEDULES C AND C(1) ²³⁹[EXCLUDING THOSE SPECIFIED IN CDS SCHEDULE X) SCO

1,...... is hereby ²[licensed to sell, stock or exhibit or offer for sale, or distribute] by wholesale on the premises situated at.......the following categories of drugs specified in Schedules C and C(1) ³[excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

Categories of drugs

- ⁴[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]
- ⁵[2A. The sale shall be made under the personal supervision of a competent person. (Name of the competent persons.)]

Date	Licence No
	Licensing Authority
	Conditions of Licence
	This licence shall be displayed in a prominent place in a part of the es open to the public.
the current the current the current the lice such per the lice the	the licensee wants to sell, stock and exhibit for sale or distribute during rency of the licence additional categories of drugs listed in Schedule C(l) uding those specified in Schedule X] but not included in this licence, he apply to the licensing authority for the necessary permission. This will be deemed to extend to the categories of drugs in respect of which ermission is given. This permission shall be endorsed on the licence by unsing authority. No drug shall be sold unless such drug is purchased under a cash or nemo from a duly licensed dealer or a duly licensed manufacturer. sale of any drug shall be made for purposes of resale to a person not the requisite licence to sell, stock or exhibit for sale or distribute the
Provide	ed that this condition shall not apply to the sale of any drug to—
	(a) an officer or authority purchasing on behalf of Government,
	(b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or
	² [(c) a manufacturer of hydrogenated vegetable oils, beverages, confectionery and other non-medicinal products, where such drugs are required for processing these products.]

3. This licence is subject to the conditions stated below and to the provisions

of Drugs and Cosmetics Act, 1940, and the Rules thereunder.

³[5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Lisensing Authority in the name of the firm with the changed constitution.]

⁴[FORM 21BB

(See rule 62D)

LICENCE TO SELL BY WHOLESALE OR TO DISTRIBUTE DRUGS SPECIFIED IN SCHEDULE C AND SCHEDULE C(I) TO THE DRUGS AND COSMETICS RULES, 1945 FROM A MOTOR VEHICLE

1,	and is hereby licensed to sell by wholesale, or
61	chedule C and Schedule C(l) from the vehicle
	assigned under Motor Vehicles Act, 1939
	ed below to the provisions of the Drugs and
Cosmetics Act, 1940 and the rule	SKENDARKINAN - V.
Ö	V N (\(\) \(\) \(\)
5ro TPI 1: 1 CDSC(O LAND MAL CDSCO 11 1 1 11 . 1.1

³[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

3. Categories of drugs	
Date	Licence No
	Licensing Authority

Conditions of Licence

- 1. This licence shall be displayed in a prominent place on the vehicle.
- 2. No drugs to which this licence applies shall be sold by wholesale or distributed unless the precautions as are published by the licensing authority

from time to time in the Official Gazette have been observed throughout the period during which it has been in the possession of the licensee.

- 3. If the licensee wants to sell by wholesale or distribute during the currency of the licence additional categories of drugs listed in Schedule C and Schedule C(l) not included in this licence, he shall apply to the licensing authority for necessary permission. This licence shall be deemed to extend to the categories of drugs in respect of which such permission is given. This shall be endorsed on the licence by the licensing authority.
- 4. (i) No drug shall be sold by wholesale or distributed unless such drug is purchased under a cash or credit memo from a duly licensed manufacturer.
- (ii) No sale by wholesale or distribution of any drug shall be made for the purpose of resale to a person, not holding the requisite licence to sell, stock or exhibit for sale or distribute the drugs.

Provided that this condition shall not apply to the sale of any drug to—

- (a) an officer or authority purchasing on behalf of the Government, or
- (b) a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, or
- (c) a manufacturer of hydrogenated vegetable oils, beverages, confectionery and other non-medicinal products, where such drugs are required for processing their products.
- 5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

6. The licensee shall inform the licensing authority in writing in the event of any change in the ownership of the vehicle specified in this licence within seven days of such change.]

FORM 21C H***]

FORM 21CC ²⁴¹[***]

FORM 22 M***]

FORM 23 242 [***]

FORM 24

(See rule 69)

APPLICATION FOR THE GRANT ²⁴³[***] OF A ²⁴⁴[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN ⁴[SCHEDULES C, C(I) AND X]

Note.—The application should be accompanied by a plant of the premises.

FORM 24A

(See rule 69A)

APPLICATION FOR GRANT ²[***] OF A LOAN ³[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN "[SCHEDULES C, C(I) AND X]

of a licence to manuthe underme	facture on the premis	hereby apply forces situated atan those specified in "[Sles, 1945.	
Names of drugs (each	substance to be separa	ntely specified).	
connected with the r manufacturing premis 3. I/We enclose (a) A true cop whose manufactur (b) A true cop agree to lend the the manufacture every batch of fi finished products	oy of a letter from maring capacity is intended by of a letter from the services of their experience of each item required mished product and mass and reports of analysis	e/us to the manufacture ded to be utilised by me/us and that they aintain the register of rais separately in this behavior the products prop	ring concern fus. orn that they premises for will analyse tw materials,
(4) A fee of rupees	has been	n credited to Governme	ent under the
	Signature me of the proprietor, p	artners or Managing Di	rector as the

! Enter here the name of the applicant firm and the address or the principal place

of business

Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates.

¹[FORM 24B

(*See* rule 69)

APPLICATION FOR GRANT ²⁴⁶[***] OF A LICENCE TO REPACK FOR SALE OR DISTRIBUTION OF DRUGS, BEING DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C AND C(I) ³[EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

THAN THOSE SPECIFIED IN SCHEDULES C AND C(I) LEXCLUDING
THOSE SPECIFIED IN SCHEDULE X]
1. I/We,
licence to repack the following drugs at the premises situated at
NDARD COM
2. Names of the drugs to be repacked.
 Names of the drugs to be repacked. Name, qualification and experience of competent staff
3. Name, qualification and experience of competent staff
4. A fee of rupees forty has been credited to Government under the head of
accountCDSCO CDSCO
account
DateSignature of applicant] सत्यमेव जयते
भि _० सत्यमेव जयते क्राउ
Note.—The application shall be accompanied by a plan of the premises.
⁵ [FORM 24C
(See rule 85B)
APPLICATION FOR GRANT ²⁴⁸ [OR RENEWAL] OF A ²⁴⁹ [LICENCE
TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF
HOMOEOPATHIC MEDICINES OR A LICENCE TO MANUFACTURE
POTENTISED PREPARATIONS FROM BACK POTENCIES BY
LICENSEES HOLDING LICENCE IN FORM 20C
⁸ [1. I/We,holder of licence Noi
Form 20C hereby apply for ²⁵⁰ [grant or renewal] of licence to manufacture th
undermentioned Homoeopathic Mother Tincture/Potentised and other
preparations on the premises situated at
1 1

Names of the Homoeopathic preparations
(Each item to be separately specified).
2. Names, qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.
3. A fee of rupeeshas been credited to Government under head of account
DateSignature]
Note.—(1) Delete whichever portion is not applicable.
Note.—(1) Delete whichever portion is not applicable. (2) The application should be accompanied by a plan of the premises. (See rule 153) APPLICATION FOR THE GRANT OF A LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI
1. I/W e
2. Names of drugs categorized according to Schedule T to be manufactured (with details)
3. Names, qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic, Siddha or Unanterly
4. A fee of rupees
DateSignature
(Applicant)

Note.—The application should be accompanied by a Plan of the premises.]

²[FORM 24E

(See rule 153A)

APPLICATION FOR THE GRANT OF A LOAN LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

	DKUGS
1. I/We*,	of!hereby apply for the grant of a loan
	Ayurvedic, Siddha or Unani drugs on the premises
situated atC	C/o [#]
2. Names of drugs cates (with details).	gorized according to Schedule T to be manufactured
	ations and experience of technical staff actually facture and testing of Ayurvedic, Siddha or Unanic premises.
(a) A true copy	of a letter from me/us to the manufacturing concern
whose manufacturi	ng capacity is intended to be utilized by me/us.
	of a letter from the manufacturing concern that they
	services of their competent technical staff, equipment the manufacture of each item required by me/us and
-	aintain the registers of raw materials and finished
(c) Specimen of manufactured.	of labels, cartons of the drugs proposed to be
Government under the he	has been credited to ad of account and the relevant ransaction slip is enclosed herewith.
Date	Signature

- Enter here the name of the proprietor, partners or Managing Director as the case may be. ! Enter here the name of the applicant firm and the address or the principal place of business.
- Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates.]

FORM 24E-1
(See rule 153B)
APPLICATION FOR THE CERTIFICATE OF GOOD
MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA OR
UNANI DRUGS MANUFACTURING UNITS
100
1.I/We
of a Certificate of Good Manufacturing Practices for Ayurvedic, Siddha or
Unani drugs manufacturing on the premises situated
at
EN CONTRACTOR OF THE CONTRACTO
2. A fee of rupees
under the head of account
Challan/online transaction slip is enclosed herewith.
Date सत्यमेव जयते ignature
Date
(Applicant)
Note.—The application should be accompanied by a Plan of the premises.]
² [FORM 24F
(See rule 69)
APPLICATION FOR THE GRANT 3]***] OF A 4[LICENCE TO
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS
SPECIFIED IN SCHEDULE X AND NOT SPECIFIED IN SCHEDULES
C AND C(I)
1. I/We,hereby apply for the
⁵ [grant] of licence to manufacture on premises situated at

the undermentioned drugs, speci Drugs and Cosmetics Rules, 1945.	fied in Schedule X to the
2. Names of drugs.	
3. Names, qualifications and experience of technomanufacture and testing.	nical staff employed for
4. A fee of rupeeshas been account under the head of account	credited to Government
Date Signature	
Desi	gnation]
**LICENCE TO MANUFACTURE FOR SALE OR OF] DRUGS OTHER THAN THOSE SPECIFIED C(I) AND X] Number of licence and date of issue	e following categories of dules C, C(l) and X] to the under the Technical Staff]:— ecified)ecified)ecified and storage
for sale by the licensee of the drugs manufactured und the conditions applicable to licence for sale.	der the licence, subject to

²[3. The licence unless sooner suspended or cancelled shall remain valid

perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs

and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date	Signature			
	Designation			

³[*Licencing Authority/ "Central Licence Approving.]

* Delete whichever is not applicable.

Conditions of Licence

- 1. This licence ⁴[***] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. Any change in the [Competent Technical Staff] named in the licence shall be forthwith reported to the licensing authority.
- 3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 69(5). This licence will be deemed to extend to the categories so endorsed.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

FORM 25A

(See rule 70A)

LOAN ^LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN $\frac{251}{2}[SCHEDULES\ C,\ C(I)\ AND\ X]$

1. Number of licence and date of issue
2s hereby granted a loan licence to manufacture the following drugs being drugs other than those specified in
² [Schedules C, C(l) and X] to the Drugs and Cosmetics Rules, 1945, on the
premises situated at
supervision of the following ²⁵² [Competent Technical Staff]:—
(a) ³ [Competent Technical Staff] (Names)
(b) Names of drugs
3. The licence authorises the sale by way of wholesale dealing by the
licensee and storage for sale by the licensee of the drug manufactured under the
licence subject to the conditions applicable to licences for sale.
⁴ [4. The licence, unless sooner suspended or cancelled, shall remain valid
perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years or
as needed as per risk based approach.]
5. The licence is subject to the conditions stated below and to such other
conditions as may be specified in the Rules for the time being in force under
Drugs and Cosmetics Act, 1940.
Date
Designation
Conditions of Licence

- 1. This licence and ²⁵³[***] shall be kept on the approved premises and shall be produced on the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. Any change in the ³[Competent Technical Staff] named in the licence shall be forthwith reported to the licensing authority.
- 3. If the licensee wants to undertake during the currency of the licence to manufacture for sale additional drugs he should apply to the licensing authority for the necessary endorsement to the licence as provided in Rule 69A. This licence will be deemed to extend to the drugs so endorsed.
- 4. The licensee shall inform the licensing authority in writing in the event of any changes in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]

CDSCGEORM 25BDSCO

(See rule 70)

LICENCE TO REPACK FOR SALE OR DISTRIBUTION OF DRUGS BEING DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C AND C(I) ²[EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

1		of	• • • • • • • • • • • • • • • • • • • •		is hereby g	rante	d a li	cence to re	pack the
following	drugs	for	sale	or	distribution	on	the	premises	situated
atunder the supervision of the following competent staff:									

(a) Name of drugs to be repacked.

Number of licence and date of issue.....

- (b) Names of competent staff.
- ³[2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs

Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

- 3. The licence authorises the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs repacked under the licence subject to conditions applicable to licence for sale.
- 4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date	Signature

Conditions of Licence

- 1. This licence ²⁵⁴[***] shall be kept on the licensed premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. Any change in the competent staff named in the licence shall be forthwith reported to the licensing authority.
- 3. If the licensee wants to repack for sale or distribution additional items he should apply to the licensing authority for the necessary endorsement to this licence. The licence shall be deemed to extend to only those items so endorsed.
- 4. The drugs repacked under this licence shall bear on their label, apart from other particulars required by these Rules, the name and address of the licensee and the number of the licence under which the drug is repacked preceded by the words 'Rpg. Lic. No.'
- 5. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in tire name of the firm with the changed constitution.]

¹[FORM 25C

(See rule 85D)

²[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] HOMOEOPATHIC MEDICINES

Number of licence and date of issue
1. ³ [I,, of*who holds a licence in Form 20C is hereby licensed to manufacture the under mentioned Homoeopathic Mother Tincture/potentised and other preparations on the premises situated at under the direction and supervision of following technical staff:—
Names of the Homoeopathic preparations.
(Each item to be separately specified) Names of the Technical Staff
Designation

* Delete the words 'who holds a licence in Form 20C' in the case this is not applicable.

Conditions of Licence

- 1. This licence and any certificate of renewal in force shall be kept on the premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. Any change in the technical staff named in the licence shall be forthwith reported to the licensing authority.

⁴[3. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.]]

¹[FORM 25D

(See rule 154)

LICENCE TO MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

No. of Licence and date of issue
CTANDARD CONTR
1sis/are hereby licenced to manufacture the
following Ayurvedic, Siddha or Unani drugs on the premises situated
at under the
direction and supervision of the following competent technical staff:—
(a) Competent Technical staff (Names) CDSCO
(b) Names of drugs categorized as per Schedule T (each item to be separately
specified) with specific Product Code/QR Code for each approved drug.
HEALTH, GOVERNME
2. The licence shall be in force from
3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.
Date Signature
Designation

Conditions of Licence

1. Any change in the Technical staff named in the licence shall be forthwith reported to the Licensing Authority.

- 2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
- 3. The licencee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.
- 4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.
- 5. The licence is issued only after fulfillment of the requirements of Good Manufacturing Practices (GMP) of Ayurveda, Siddha or Unani drugs as laid down in Schedule T of the Drugs Rules, 1945. DSCO

² **FORM 25**E

(See rule 154A)

LOAN LICENCE TO MANUFACTURE FOR SALE AYURVEDIC, SIDDHA OR UNANI DRUGS

1. Number of Licence.	date of issue	•••
2	of	is
• •	cence to manufacture for sale Ayurvedic, Siddha, premises situated at	
C	under the direction and supervision of	
(a) Expert Technical sta	aff (Names)	

(b) Names of drugs categorized as per Schedule T (each item to be separately specified) with specific Product Code/QR Code for each approved drug.

4.	The licence is subject to the conditions stated below and to such other
conditi	ons as may be specified in the Rules for the time being in force under the
Drugs	and Cosmetics Act. 1940.

The licence shall be in force from.

3.

Date	Designation
	Signature

Conditions of Licence

- 1. Any change in the technical staff named in the licence shall be forthwith reported to the Licensing Authority.
- 2. This licence shall be deemed to extend to such additional items as the licencee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority
- 3. The licencee shalf inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.
- 4. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in five years or as needed as per risk based approach.]

¹[FORM 25F

(See rule 70)

²[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS SPECIFIED IN SCHEDULE X AND NOT SPECIFIED IN SCHEDULES C AND C(1)

1sis hereby licensed to manufacture at the premises situated atthe following drugs specified in Schedule X to the Drugs Rules, 1945.
2. Name of drugs.
3. Names of approved ²⁵⁵ [Competent Technical Staff].
4. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale. 5. The licence shall be in force from
Licence No Designation
¹ [Licensing Authority]
*Central Licence Approving Authority]
* Delete whichever is not applicable.

Conditions of Licence

1. This licence ²⁵⁶[***] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

- 2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule X not included above, he should apply to the licensing authority for the necessary endorsement to this licence. This licence shall be deemed to extend to only those so endorsed.
- 3. Any change in the ²⁵⁷[Competent Technical Staff] shall be forthwith reported to the licensing authority.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.
- ⁴[5. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]
- 6. The licensee shall not manufacture drugs covered by this licence for use as 'Physician's Samples'.]

FORM 26 258 [***]

FORM 26A ²⁵⁹[***]

FORM 26B ²⁶⁰[***]

FORM 26C

(See rule 85G)

CERTIFICATE OF RENEWAL OF LICENCE TO MANUFACTURE FOR SALE OF HOMOEOPATHIC MEDICINES

1.	Certified	that	licence		Nogranted				on
the		to	. for	the	manufacture	for	sale	of	the

Homoeopa at				-				-		ted
2. Names	s of tec	hnica	l staff.	•••••	•••••	•••••	•••••	•••••	•••••	
¹ [3. Nat specified).					(each	item	to	be	separate	ely
Date	•••••	•••••		•••••	Signa	ture	•••••	•••••		
						Designa	tion	•••••	•••••	••••
				² [FO]	RM 26D					
				•	rule 155)					
	_ ~				DD. 00				CTURE	4
FO	OR SAL	E O	FAYU	RYEDR	C/SPODE	IA OR U	JNAN	I DRU	JGS	
1. Conthe	s of tec	Myurd has hnica gs (ea	been staff.	renewed n to be se	tinani D from	specified	ine pros	emises	s situated	
						Designa	tion	•••••	•••••]
				(See ru F RENEV SALE OF	RM 26E ale 155A) VAL OF VAYURV RUGS	LOAN			TO R UNANI	I
1. Cert drugs at renewed fr	the pre	.to emise:	s situa	for the	manufact	cure of A	Ayurve	edic/Si	iddha/Una	ani

2. Names of technical staff
DateSignature
Designation
¹ [FORM 26E-I
(See rule 157B)
CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP)
TO MANUFACTURER OF AYURVEDA, SIDDHA OR UNANI DRUGS
Certified that manufacturing unit licensee, namely
situated atState Licence No
comply with the requirements of Good Manufacturing Practices of Ayurveda
Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetics
Rules, 1945.
Siddha-Unani drugs as laid down in Schedule T of the Drugs and Cosmetics Rules, 1945. This certificate is valid for a specified of five years and the Good
Manufacturing Practices (GMP) is valid for the various dosage forms of
Rasaushadhis, as follows:]
DatedCDSCOSignature
Place Designation Designation
Licensing Authority for Ayurveda/ Siddha/'Unani Drugs.
³ [FORM 26E2-I
(See rule 158C)
State Drug Controller or Licensing Authority for Ayurveda, Siddha and
Unani Medicines Name of the State or Union territory
Free Sale Certificate
Free Sale Certificate
It is certified that M/s(Name of the company)situated
at(Address)is holding valid Ayurvedic/Siddha/Unani Drug
Manufacturing Licence Numberand certificate of Good Manufacturing
Practices for the State or Union territory of

It is also certified that the manufacturing plant situated at......(Address)...... in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

The firm has been permitted under Licence Number......to manufacture and market the following products (attach list of products, if multiple) freely for sale in India under the provisions of the Drugs and Cosemtics Act, 1940 and the rules thereunder.

	(i)
	(ii)
	(iii)
Date :	(Seal of issuing Officer) (Seal of issuing Officer) (Signature and Name) State Drug Controller/Licensing Authority Address Name of State or Union territory

State Drug Controller or Licensing Authority for Ayurveda, Siddha and Unani Medicines Name of the State or Union territory......

Free Sale Certificate

It is also certified that the manufacturing plant situated at......(Address)...... in which the Ayurvedic or Unani or Sidhha products are manufactured, conforms to the requirement of Good Manufacturing Practices and is subjected to inspection as per rules.

multiple) freely for sale in India under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder.
(i)
(ii)
(iii)
Date: (Seal of issuing Officer): (Signature and Name)
State Drug Controller/Licensing Authority
Address
Name of State or Union territory
² FORM 26 E3
(See rule 158C)
State Drug Controller or Licensing Authority for Ayurveda, Siddha and
Unani Medicines Name of the State or Union territory
It is certified that M/s (Name of the company)situated at
It is certified that M/s (Name of the company)situated at
(Registered Address) holding valid Ayurvedic/Siddha/Unani
Drug Manufacturing Licence Numberin Form 25D/25E and valid
certificate of Good Manufacturing Practices/valid Good Manufacturing
Practices certificate of principal or original manufacturer for the State or Union
territory of
As per the records of the State Drug Controller or Licensing Authority, as it may be, and affidavit (Annexure I) given by the company, the firm has not been convicted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder in the State or Union territory of, during the last three years of the issuing of this certificate.
This certificate shall be valid only for one year from the date of issue.
Date:(Seal of issuing Officer)

The firm has been permitted under Loan Licence Number.....to

manufacture and market the following products (attach list of products, if

(Signature and Name)
State Drug Controller/Licensing Authority for
Ayurveda, Siddha and Unani Medicines.
Address
Name of State or Union territory
ANNEXURE-1
(Proforma of Affidavit to be executed on appropriate non-judicial stamp
paper of minimum value and attested by Notary Public)
I
I, s/O age working as
of
to do hereby solemnly affirm and declare as under:
1. That I, in the capacity of Authorized Signatory of (name and
address Skiles States of the control
of the company), am duly competent to depose and verify the present
of the company), am duly competent to depose and verify the present affidavit.
CDSCO CDSCO
2. That I apply for Non-conviction Certificate on behalf of M/s
3. That I declare that I am aware of the details of my organization and day to
3. That I declare that I am aware of the details of my organization and day to day activities fromto
TETH, GOVE
4. That I hereby undertake that the Non-Conviction Certificate, if issued, will
be utilized for the bona fide purpose only.
5. I declare that the aforesaid firm is not convicted under the Drugs and
Cosmetics Act, 1940 and rules thereunder during the last three years.
6. That it is my true statement.
Signature of Deponent
Verification
Varified at (Dlace and State) today on this day of
Verified at (Place and State)
(month)(Year) that the contents of the above affidavit are true to my

Knowledge and belief and no part of it is false and nothing has been concealed there from.

Signature of Deponent

Witness with	Address			
1	•••••			
2	•••••			
	1	FORM 26 E	4	
		(See rule 170)		
APPLICA	TION FORM FO	R ADVERTIS	SEMENT OF A	AYURVEDIC,
		AND UNAN		,
		(ANDARD CON)		
1.1signatory o	ation may be made(name of the f g company) Licens f for considerations:	only for one a e applicant wit(name se number on of follow	h designation) and full a valid	ddress of the
Ayurvedic/ Siddha/	including		Language of advertisement	

- 2. The prescribed fee of rupees one thousand has been deposited to the Government under the head of account......and the relevant Treasury Challan is enclosed herewith.
- 3. Copies of the following documents are attached—
- i) Valid license

ii)iii)iv)v)vi)	References of indications/claims Proof of safety Proof of efficacy Quality standards Any other (please specify)	
	a b	
	C	
Date.	e Signature Address and con	(Applicant)
	¹ [FORM 26 E5	,
ST	[See rule 170] TATE LICENSING AUTHORITY FOR AYURVEDIC, SID	DHA OR
	ne of the State or Union territory	
It is situat drug	s recorded that M/s	/ company) dha / Unani
drug)	Following contents of the intended advertisement for the	
licens	The advertisement contents as above are valid till the validity onse. Invalid advertisement or any distortion in the contents of a lable for legal action as per rules.	
within	Following clarification with relevant supporting information in thirty days of issue of this communication, failing which I be declined and application fee forfeited.—	

(c) Application datedis hereby declined due to following reason(s)—

any form.		
Date	State Licens	(Signature and Name) sing Authority/Drug Controller e or Union territory]
	FORM 26F ²⁶² [***]
	¹ [FORM 26G	
² [BLOOD CENTE	-	WHOLE HUMAN BLOOD
	PREPARATION FOR SALI	
for preparation of hereby renewed with 2. Name(s) of item 1	its components at the premi h effect fromto CDSCO Ses: सत्यमंव जयते Competent Technical staff	to M/sfor of whole human blood and/or ses situated atis
Date	Signature	
		e and DesignationLicensing Authority/ ving Authority
* Delete, whichever	is not applicable	

Note: The permission shall not be reflected or shown in the advertisement in

FORM 26H ⁴[***]

⁵[FORM 26-I

(See rule 122-1)

CERTIFICATE OF RENEWAL OF LICENCE FOR MANUFACTURE OF BLOOD PRODUCTS

Certified that licence I	No	granted on		to M/s
for manufacture of bloc	od products	at the premises		ed atis hereby
renewed with effect fro	m	to		
2. Name(s) of item(s):				
1				
2				
3. Name(s) of Compete	nt Technic	al staff		responsible for testing 1
(a) responsible for man	ufacturing		o(b)	responsible for testing
1	74. X		T. C.	1
2	CDSCO	CDS	CO	2 2
2Date	■	Signature	es	ţ
	TO PL	महामेव ज्यावे Na	me ar	nd Designation
	OFHE	ALTU TUERNMEN		Licensing Authority/
		Central I	Licen	ce Approving Authority]
		[FORM 26J		
	See rules 12	22G, 122H, 122-	1, 122	2P]
				OR COLLECTION,
,	,			G AND RELEASE OF
UMBII	LICAL CO	ORD BLOOD S'	TEM	CELLS
M/sfor release of umbilical co	collection, ord blood st	processing, te	sting, premi	nted onto storage, banking and ises situated atis
hereby renewed with ef			• • • • • • • • •	•
1 Name(s) of competer	nt Technica	al Staff·		

1
2
3
Signature
Designation
Licensing Authority
Date
Central Licence Approving Authority]
FORM 26J
² [***]
FORM 27 APPLICATION FOR GRANT [***) OF A 263 [LICENCE TO
APPLICATION FOR GRANT 1888 OF A 263 ILICENCE TO
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS
SPECIFIED IN SCHEDULES C AND C(1) 264 [EXCLUDING THOSE
SPECIFIED INSPART XB AND SCHEDULE X]
6068 0040 100 100 100 100 100 100 100 100 10
1. I/We,hereby apply for the ²⁶⁵ [grant] of a licence to
manufacture on the premises situated व तायतthe undermentioned drugs,
being drugs specified in Schedules C and C(1), 3 [excluding those specified in
³ [Part XB and] Schedule X] to the Drugs Rules, 1945,
Name of drugs(each item to be separately specified).
2. The names, qualifications and experience of the expert staff responsible
for the manufacture and testing of the above-mentioned drugs:
(a) Name(s) of staff responsible for test
(b) Name(s) of staff responsible for manufacture
3. The premises and plan are ready for inspection/will be ready for inspection

on.....

4. A fee of rupeesand an inspection fee of rupeeshas been credited to Government under the head of
account
DateSignature
Designation
Note.—The application shall be accompanied by a plan of the premises.
FORM 27A
(See rule 75 A)
APPLICATION FOR GRANT ² [***] OF A LOAN ² [LICENCE TO
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS
SPECIFIED IN SCHEDULES C AND C(1) ³ [EXCLUDING THOSE
SPECIFIED IN 266 [PART XB AND] SCHEDULE X]
SPECIFIED IN ²⁶⁶ [PART XB AND] SCHEDULE X] 1. I/We*,
of loan licence to manufacture on the premises situated at
C/o [#] the undermentioned drugs, being drugs specified in Schedules C and C(1) ³ [excluding those specified in ⁴ [Part XB and] Schedule X
to the Drugs Rules, 1945.
Name of drugs (each substance to be separately specified).
2. The names, qualifications and experience of the expert staff actually
2. The names, qualifications and experience of the expert staff actually
connected with the manufacture and testing the specified products in the
manufacturing premises.
(a) Name(s) of expert staff responsible for manufacture
(b) Name(s) of expert staff responsible for testing
3. I/We enclose
(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilised by me/us.
(b) A true copy of a letter from the manufacturing concern that they agree to

lend the services of their expert staff, equipment and premises for the

manufacture of each item required by me/us and that they will analyse ever}' batch of finished products and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.

(c) Specimens of labels, cartons of the products proposed to be manufactured.
4. A fee of rupeeshas been credited to Government under the head of account
DateSignature
* Enter here name of the proprietor, partners or Managing Director as the case may be.
! Enter here name of the applicant firm and the address of the principal place of
business.
Enter here the name and address of the manufacturing concern where the
manufacture will be actually carried out and also the licence number under which the letter operates. Teorm 27B
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS
SPECIFIED IN SCHEDULES C. E(I) AND A
SPECIFIED IN SCHEDULES C. C(I) AND X 1. I/We,
of a licence to manufacture on the premises situated atthe
undermentioned drugs, specified in Schedules C, C(l) and X to the Drugs Rules 1945.
2. Names of drags.
3. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the abovementioned drugs.
(a) Name(s) of staff responsible for test.
(b) Name(s) of staff responsible for manufacture.

4. The premises inspection	and plant* are ready for inspection/will be ready for
on	
	rupeesand an inspection fee of the descriptionhas been credited to the Government under the head of the control of the description
Date	Signature
The application shall	be accompanied by a plan of the premises.]
* Delete whichever i	s not applicable.
OPERATION OF WHOLE BY A SHORE WHOLE BY A SHORE WHOLE BY A SHORE WHOLE BY A SHORE WHO A SHO	TALIH, GOVERN
1.	
2.	
3. The name(s), are as under:	, qualification and experience of competent Technical State
(a) Name(s	s) of Medical Officer.
(b) Name(s	s) of Technical Supervisor.
(c) Name(s	s) of Registered Nurse.

(d) Name(s) of [Blood Centre] Technician.
4. The premises and plant are ready for inspection/will be ready for inspection
on
5. A licence fee of rupeesand an inspection fee of rupeeshas been credited to the Government under the Head of Account(receipt enclosed).
Signature
Dated Name and Designation
* Delete whichever is not applicable.
Note 1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.

Note 2. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal/ Sub-Zonal Officers of the Central Drugs Standard Control Organisation.]

²[FORM 27D

(*See* rule 75)

APPLICATION FOR GRANT ³[***] OF A LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF "[LARGE VOLUME PARENTERALS/ SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS] EXCLUDING THOSE SPECIFIED IN SCHEDULE X

1.	I/We,.	• • • • • • • • • • • • • • • • • • • •	of.		h	ereby a	appl	y for the 5	'[grant]	of a
lice	ence to	manufactu	ire for	sale or	distribution	n on t	the j	premises	situated	d at
••••		, the	underi	mention	ed ⁴ [Large	Volur	me l	Parenteral	ls/Sera	and
Va	.ccine/R	ecombinan	t DNA	(r-DNA)) derived dr	ugs], s	spec	ified in S	chedule	es C
ano	d C(1) to	the Drugs	Rules, 1	1945.						

2. Name(s) of drug(s).....(each item to be separately specified).

3. The name(s), qualifications and experience of the competent technical staff
responsible for the manufacture of the above mentioned drugs.
(a) Name(s) of staff responsible for testing
(b) Name(s) of staff responsible for manufacture
4. The premises and plant are ready for inspection/will be ready for inspection
on:
5. A fee or rupeesand an inspection fee of
rupeeshas been credited to the Government under the Head of
Account
Signature
DateDesignation
Notes 1. The application is to be accompanied by a plan of the premises; list of
equipments and machinery to be employed for manufacture and testing;
memorandum of association/constitution of the firm; copies of qualification and
experience of competent technical staff and documents relating to ownership or
tenancy of the premises.
Notes 2. A copy of the application together with relevant enclosure shall also be
sent each to Central Licence Approving Authority and concerned Zonal/Sub-
Zonal Officers of Central Drugs Standard Control Organisation.]
O TIFORM 27DA
See mule 75A)
APPLICATION FOR GRANT 272 (***1 OF A LOAN LICENCE TO
MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE
VOLUME PARENTERALS/SERA AND VACCINE/ RECOMBINANT
DNA (R-DNA) DERIVED DRUGS EXCLUDING THOSE SPECIFIED
UNDER SCHEDULE X
UNDER SCHEDULE A
1. I/We*,hereby
apply for the ³ [grant] of a loan licence to manufacture on the premises situated
at c/o @ the under-mentioned drugs being Large
Volume Parenterals/Sera and Vaccine/ Recombinant DNA (r-DNA) derived
drugs specified in Schedules C, C(l), excluding those specified in Schedule X to
the Drugs Rules, 1945.
me Diago Raico, 1775.

	ame(s) tely spe	_			••••••	•••••	(each	item to) be
	3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above-mentioned drugs.								
	(a) testing	Name(s)		competent	technical	staff	respo	onsible	for
	(b) manu	Name(s)		competent	technical	staff	respo	onsible	for
4. I/v	ve enclo	ose:							
(a) A true copy of a letter from letter from me/us to manufacturing concern whose manufacturing capacity is intended to be utilized by me/us. (b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and they will analyse every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf. (c) Specimens of labels, cartons of the drugs proposed to be manufactured. The content has been credited to Government under the head of account									
Date	••••••	•••••••••••••••••••••••••••••••••••••••	•••••	•••••	Signature.	•••••	••••••	••••	
					De	esignat	ion	••••••	•••••
* En be.	tre here	name of t	he pr	oprietor, par	tners or Ma	naging	g Direc	tor, as	may
# Ente		name of the	appli	cant firm and	d the addres	s of the	e princi	pal plac	e of

@ Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the licence number under which the latter operates".

¹[FORM 27E

(See rule 122F)

APPLICATION FOR GRANT/RENEWAL OF LICENCE TO MANUFACTURE BLOOD PRODUCTS FOR SALE OR DISTRIBUTION

	I/We, ence/renewal of nufacture blood p	licence nu		date	ed			
2.	Name(s) of item							
	1.	esst	ANDARD CONTRO	26 _				
	2.	OF ORIUS	ANDARD CONTRO	ORGANIZ				
	3. The name(ion and experi		Compe	etent	Techni	ical
	Staff as under:		CDS	Z	•			
	(a) responsi	ible for manu	facturing (b) r	esponsib	ole for t	esting	g	
	1.	STRY OF HE	सत्यमेव जयते ^{EALTH} , GOVERNIE	MI.				
	2.		TH, GOV	2.				
4.	The premises an	d plant are re	ady for inspection	on/will b	e ready	for i	nspecti	ion
on.								
••••	A licence fee of the licence fee	credited to t			-		-	
Dat	ted		S	ignature		•••••		••••
			Na	me and I	Designa	ition		
					_			

^{*} Delete whichever is not applicable.

- **Note 1.** The application shall be accompanied by a plant of the premises, list of machinery and equipment for manufacture of blood products, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the said premises.
- **Note 2**. A copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal/Sub-Zonal Officers of the Central Drugs Standard Control Organisation.]

¹[FORM 27F

(See rule 122F)

APPLICATION FOR GRANT/RENEWAL* OF LICENCE FOR COLLECTION, PROCESSING, TESTING, STORAGE, BANKING AND RELEASE OF UMBILICAL CORD BLOOD STEM CELLS

I/Wehereby apply for the grant of
l/We
collection, processing, testing, storage, banking and release of umbilical cord
blood stem cells on the premises situated at
2. Name(s), qualification and experience of competent Technical Staff are as
under: सत्यमेव जयते 1. Medical Director HEALTH, GOVERNMENT OF
1. Medical Director HEALTH, GOVERNME
2. Laboratory In-charge
3. Technical Supervisor
4. Cord Blood Bank Technician(s)
3. The premises and plant are ready for inspection/will be ready for inspection
on
4. A licence fee of rupees and an inspection fee of
rupees has been credited to the Government under the Head of Account (receipt enclosed)
Signature

DatedName & Designation
"Delete whichever is not applicable.
Note. —1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, testing, storage, banking and release of umbilical cord blood stem cells, memorandum of association/constitution of the Firm, copies of certificate relating to educational qualification and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.
2. A copy of the application together with the relevant enclosure shall also be sent to the Central Licence Approving Authority and to the Zonal/Sub-Zonal Officers concerned of the Central Drugs Standard Control Organization.]
(See rule 76) ² [LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS SPECIFIED IN SCHEDULES C AND C(I) ³ [EXCLUDING
THOSE SPECIFIED IN SCHEDULE X] CDSCO CDSCO
Number of licence and date of issue
1
Names of drugs

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the condition application to licence for sale.

2. Names of approved "[Competent Technical Staff].....

¹[4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs

and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of issue	Signature
	Designation

²[*Licensing Authority/Central Licence Approving Authority]

* Delete whichever is not applicable.

Conditions of Licence

- 1. This licence ²⁷³[***] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedules C and C(l) "[excluding those specified in Schedule X] not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 753. This licence will be deemed to extend to the items so endorsed.
- 3. Any change in the ²⁷⁴[Competent Technical Staff] shall be forthwith reported to the licensing authority.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

FORM 28A

(See rule 76A)

LOAN $\frac{275}{1}$ [LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS SPECIFIED IN SCHEDULE C AND C(I) $\frac{276}{1}$ [EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

1. Number of licence and date of issue
2is hereby granted a loan licence to manufacture on the premises situated at
following drugs being drugs specified in Schedules C and C(l) 277 [excluding
hose specified in Schedule X] to the Drugs Rules, 1945.
Names of drugs
3. Names of approved ²⁷⁸ [Competent Technical Staff]
³ [3A. The licence, unless sooner suspended or cancelled, shall remain valid
perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.] 4. The licence authorises the sale by way of wholesale dealing by the
4. The licence authorises the sale by way of wholesale dealing by the
icensee and storage for sale by the licensee of the drugs manufactured under
he licence subject to the conditions applicable to licence for sale.
5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.
Date of issueSignature
Designation

Conditions of Licence

- 1. This licence ²⁷⁹[***] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. If the licensee wishes to undertake during the currency of the licence to manufacture any drug specified in Schedules C and/or C (1) ⁴[excluding those specified in Schedule X] not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 75A. This licence will be deemed to extend to the items so endorsed.
- 3. Any change in the ²[Competent Technical Staff] shall be forthwith reported to the licensing authority.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

¹[FORM 28B

OF DRUGS SPECIFIED IN SCHEDULES C, C(1) AND X

²[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION

No. of licence	• • • • • • • • • • • • • • • • • • • •	••••			
1is premises situated at	•				
C, C(l) and X to the Drugs Rules, 1		8	<i>6</i>		
Name of drugs	•				

2. Names of approved expert staff.

- 3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licence for sale.
- ³[4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]
- 5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

- 1. The licence ⁵[***] shall be kept at the approved premises and shall be produced at the request of the Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule X not included above, he should apply to the licensing authority for the necessary endorsement as provided in rule 75(4). This licence will be deemed to be applicable to the items so endorsed.
- 3. Any change in the expert staff shall be forthwith reported to the licensing authority.
- 4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on

which the change takes place unless, in the meantime a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

- 5. The licensee shall furnish lo the licensing authority copies of invoices of sales made to dealers.
- 6. The licensee shall not manufacture drugs specified in Schedule X covered by this licence for use as "Physician's Samples".]

¹[FORM 28C

(See rule 122G)

LICENCE TO OPERATE A ²⁸⁰[BLOOD CENTRE] FOR COLLECTION, STORAGE AND PROCESSING OF WHOLE HUMAN BLOOD AND/OR* ITS COMPONENTS-FOR SALE OR DISTRIBUTION

AND/OR* ITS COMPONENTS FOR SALE OR DISTRIBUTION
1. Number of Licence date of issue at the premises situated
2. M/ss hereby licensed to collect, store process and distribute
whole blood and/or its components.
3. Name(s) of the item(s):
3. Name(s) of the item(s): 1. सत्यमेव जयते 2
2.
4. Name(s) of Competent Technical Staff:
1.
2.

- 5. The licence authorises licensee to collect, store, distribute, and processing of whole blood and/or blood components subject to the conditions applicable to this licence.
 - 6. The licence shall be in force from..... to

7.	The licence shall be subject to the conditions stated below and to such
other	conditions as may be specified from time to time in the Rules made under
the D	rugs and Cosmetics Act, 1940.

Dated	Signature
	Name and Designation
	*Licensing Authority/
	*Central Licence Approving Authority

Conditions of Licence

- 1. The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components from the blood collected from such a donor.
- 2. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 3. Any change in the technical staff shall be forthwith reported to the licensing authority and/or Central Licence Approving Authority.
- 4. The licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the licensing authority and /or Central Licence Approving Authority in the name of the firm with the changed constitution.]

^{*} Delete, whichever is not applicable.

¹[FORM 28D

(*See* rule 76)

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF ²[LARGE VOLUME PARENTERALS/SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS] SPECIFIED IN SCHEDULE C AND C(I) EXCLUDING THOSE SPECIFIED IN SCHEDULE X

and Date of issue

Number of licence

at the following ²⁸¹ [Large Volume Parenterals/Sera and Vaccine/Recombinant DNA (r-DNA) derived drugs] specified in Schedule C	Tumber of nechecand Date of issue
Vaccine/Recombinant DNA (r-DNA) derived drugs] specified in Schedule C	1is hereby licensed to manufacture at the premises situated
	at the following ²⁸¹ [Large Volume Parenterals/Sera and
and C(1) excluding those specified in Schedule X to the Drugs and Cosmetics	Vaccine/Recombinant DNA (r-DNA) derived drugs] specified in Schedule C
and e(i) energeing mose specified in seneggie in to the Brags and cosmolog	and C(l) excluding those specified in Schedule X to the Drugs and Cosmetics
Rules, 1945.	Rules, 1945.
specified)	3. Name(s) of competent technical staff
(a) responsible for manufacturing (b) responsible for testing	(a) responsible for manufacturing (b) responsible for testing
1. सत्यमेव जयते सत्यमेव	1. सत्यमेव जयतै स्तर्भे
1. सत्यमेव जयते सत्यमेव जयते । सत्यमेव । सत्य	2. HEALTH, GOVERNME

- 4. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.
- ³[5. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]
- 6. The licence shall be subject to the conditions stated below and to such other conditions as shall be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

	Signature
	Designation
	Licensing Authority/Central Licence Approving Authority
Date	

C: - - - 4-- - -

Conditions of Licence

- 1. The licence ²⁸²[***] shall be kept on the approved premises and shall be produced at the request of an inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. If the licensee wishes to undertake during the currency of the licence to manufacture any drug specified in Schedule C and/or C(l) excluding those specified in Schedule X not included above, he should apply to the licensing authority and/or Central Licence Approving Authority for the necessary endorsement as provided in the Rules. This licence shall be deemed to extend to the items so endorsed.
- 3. Any change in the competent technical staff named in the licence shall be forthwith reported to the licensing authority and/or Central Licence Approving Authority.
- 4. The Licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been applied for alongwith prescribed fee and necessary documents to the licensing authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

¹[FORM 28DA

(See rules 76A, 78A, 83AA)

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF LARGE VOLUME PARENTERALS/SERA AND VACCINE/RECOMBINANT DNA (R-DNA) DERIVED DRUGS EXCLUDING THOSE SPECIFIED UNDER SCHEDULE X

licence.....and

Number

of

issue
1 of is hereby granted a loan licence
to
manufacture on the premises situated at c/o the
following drugs being Large Volume Parenterals Scra and Vaccine/Recombinant DNA (recombination)
drugs being Large Volume Parenterals/Scra and Vaccine/Recombinant DNA (r-
DNA) derived drugs specified in Schedules C, C(l), excluding those specified in
Schedule X to the Drugs and Cosmetics Rules, 1945.
1. Names of drugscosco
2. Name (s) of competent technical staff
भू सत्यमेव जयते क्र [©]
perpetually. However, the compliance with the conditions of licence and the
provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs
and Cosmetics Rules, 1945 shall be assessed not less than once in three years of
as needed as per risk based approach.]
4. The licence authorizes the sale by way of wholesale dealing by the
licensee and storage for sale by the licensee of the drugs manufactured under
the licence subject to the conditions applicable to licence for sale.
5. The licence is subject to the conditions stated below and to such other
conditions as may be specified in the rules for time being in force under the
Drugs and Cosmetics Act, 1940.
Date
Signature
Designation
Licensing/ Authority

date

of

Conditions of licence

- 1. This licence ³[***] shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. Any change in the competent technical staff shall be forthwith reported to the Licensing Authority and Central License Approving authority.
- 3. If the licensee wants, during the currency of the licence, to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority and/or Central Licence Approving Authority for the necessary endorsement as provided in the rules. This licence will be deemed to extend to the items so endorsed TANDARD CONTROL
- 4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

¹[FORM 28E

(See rule 122G)

LICENCE TO MANUFACTURE AND STORE BLOOD PRODUCTS FOR SALE OR DISTRIBUTION

1.	Number	of	licence	date	of	issueat	the
premise	s situated	at	•••••				

- 2. M/s.....is hereby licensed to manufacture, store, sell or distribute the following blood products:—
 - 3. Name(s) of the item(s):

1.

3.	
4.	
5.	
4. Name(s) of C	ompetent Technical Staff:
(a) responsible for ma	anufacturing (b) responsible for testing
1.	1.
2.	2.
3.	UGS STANDARD COBTROL
distribute the blood p6. The licence sha7. The licence s	authorises the licensee to manufacture, store, sell or roducts, subject to the conditions applicable to this licence. Il be in force from
	Name and Designation
*	Date Licensing Authority/*Central Licence Approving Authority
	Conditions of Licence
	shall not manufacture blood products from the blood drawn l donor or paid donor.
	and any certificate of renewal in force shall be displayed on es and shall be produced at the request of an Inspector

2.

appointed under the Drugs and Cosmetics Act, 1940.

- 3. Any change in the technical staff shall be forthwith reported to the licensing authority and/or Central Licence Approving Authority.
- The licensee shall inform the licensing authority and/or Central Licence Approving Authority in writing any change in the constitution of the firm operating under the licence. In the event of any change in the constitution of the firm, the licence shall be deemed to be valid for a period of three months from the date on which the change takes place unless, a fresh licence has been taken from the licensing authority and/or Central Licence Approving Authority in the name of the firm with changed constitution.]

¹[FORM 28F

(See rules 122F to 122-1, 122.K, 122P)

LICENCE TO COLLECT PROCESS TEST STORE RANKING AND

DICERCE TO COLLECT, I ROCEDS,	, ledi, bloke, british to mid
RELEASE OF UMBILICALICO	RD BLOOD STEM CELLS
	0.
1. Number of licence	date of cissueat
	MZATI
- / // V V/A	ed to collect process, test, store,
banking and release of umbilical cord bloo	
3. Name(s) of competent Technical St	aff:
3. Name(s) of competent Technical St सत्यमेव ज 1.	पत VERNMENT
2.	
3.	
4.	
5.	
1 The licence authorises licensee to	collect process test store banking

- The licence authorises licensee to collect, process, test, store, banking and release of umbilical cord blood stem cells subject to the conditions applicable to this licence.
 - The licence shall be in force from.....to..... 5.

the Drugs and Cosmetics Act, 1940.	
	Signature
	Name & Designation
	Licensing Authority
	Central Licence Approving Authority
Dated	

other conditions as may be specified from time-to-time in the Rules made tinder

The licence shall be subject to the conditions stated below and to such

Conditions of Licence

- 1. Umbilical cord blood specific for an individual will be collected after signing an agreement with the parent(s), whose child's Umbilical cord blood is to be collected, and the cord blood bank.
- 2. Umbilical cord blood shall be collected from hospitals, nursing homes, birthing centers and from any other place where a consenting mother delivers, under the supervision of the qualified Registered Medical Practitioner responsible for the delivery.
- 3. The licence and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an inspector appointed under the Drugs and Cosmetics Act, 1940.

CDSCO

- 4. Any change in the technical staff shall be forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.
- 5. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh licence has been taken from the Licensing Authority and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]

FORM 29

(See rule 89)

LICENCE TO MANUFACTURE DRUGS FOR PURPOSES OF EXAMINATION, TEST OR ANALYSIS

1 of is hereby licensed to
manufacture the drugs specified below for purposes of examination, test or analysis at
2. This licence is subject to the conditions prescribed in Part VIII of the Drugs and Cosmetics Rules, 1945.
3. This licence shall be in force for '[three years] from the date specified below.
Name of drugs
Name of drugs Date
APPLICATION FOR LICENCE TO MANUFACTURE DRUGS FOR
PURPOSES OF EXAMINATION, TEST OR ANALYSIS
ा,
apply for a licence to manufacture the drugs specified below for purposes of examination, test or analysis at and I undertake to comply with the
conditions applicable to the licence.
Names of drugs
DateSignature
FORM 31 1 [***]

FORM 31A

²[***]

-	\sim T		-	20
1111		\mathbf{N}	1	27
г.		N IV	4	. 7 2

3[***]

FORM 32A

4[***]

FORM 33

5 [***]

FORM 33A

6[***]



FORM IN WHICH THE INSPECTION BOOK SHALL BE MAINTAINED

- (A) The cover of the Inspection Book shall contain the following particulars, namely:—
- 1. The name and address of the licensee.....
- 2. Licence number and the date up to which the licence is valid
- (B) (i) The pages of the Inspection Book shall be serially numbered and duly stamped by the licensing authority. The pages, other than the first and the last pages, shall have the following particulars:—

Name and designation of the Inspector who inspects the premises of the licensee.....

Date of Inspection	••••
--------------------	------

Observations of the Inspector
Signature of the Inspector
(ii) The first and last pages of the Inspection Book shall be endorsed by the licensing authority with the following words, namely:—
'Inspection Book maintained by M/ssituated atfor licence numberin Formunder Drugs Rules, 1945.
Seal and Signature of the Licensing Authority
Notes.—(i) Printed copy of the inspection Book may be obtained by the licensee from the licensing authority on payment.
(iii) The Inspection Book shall be maintained at the premises of the licensee. (iii) The observation made by the Drugs Inspector shall be in triplicate. The original copy shall be retained in the Inspection Book to be maintained in the premises of the licensee. The duplicate copy shall be sent to the licensing authority. The triplicate copy shall be taken as record by the Inspector.] CDSCO [FORM 36 [See rule 150 B] APPLICATION FOR GRANT 284 [****] OF APPROVAL FOR CARRYING OUT TESTS ON DRUGS/285 [****] OF APPROVAL FOR CARRYING THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/3!***] 286 [OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]
(1) I/We,
(2) *Categories of drugs, ⁶ [***]:—

(a) excluding	Drugs other than those specified in Schedules C and C(l) and also Homoeopathic Drugs:—
	1. Crude vegetable drugs.
	2. Mechanical contraceptives.
	3. Surgical dressings.
	4. Drugs requiring the use of ultraviolet/Infra Red Spectro-photometer or Chromatography.
	5. Disinfectants.
	6. Other drugs.
(b)	Drugs specified in Schedules C and C(1):
	1. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.
	2. Antibiotics _{CDSCO} CDSCO
	3. Vitamins.
	 Vitamins 4. Parenteral preparations. 5. Sterilised surgical ligature/suture.
	5. Sterilised surgical ligature/suture.
	6. Drugs requiring the use of animals for their test.
	7. Drugs requiring microbiological tests.
	8. Drugs requiring the use of Ultraviolet/Infra Red Spectro-photometer or Chromatography.
	9. Homoeopathic drugs.
(c)	Homoeopathic drugs.
(d)	¹ [***]

- (3) Names, qualifications and experience of expert staff employed for testing and the person-in-charge of testing.
- (4) List of testing equipment provided.
- (5) I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

(6)	An	inspection	fee	of	rupeeshas	been	credited	to
Gove	rnme	nt under the	head	of a	ccount			

Dated	Signature	
Datcu	Digilatuic	•••••••

EORM 37

(See rule 150C)

APPROVAL FOR CARRYING OUT TESTS ON DRUGS/²⁸⁹!***]

AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF DRUGS/¹[***] ²⁹⁰[OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY]

Number of approval and date of issue.....

(1) Approval is hereby granted to TH. GOVERNM. for carrying out tests for identity, purity, quality and strength on the following categories of drugs/²⁹¹[***] and the raw materials used in the manufacture thereof on the premises situated at......

Categories of drugs/⁵[***].

- (2) Names of approved ²⁹²[Competent Technical Staff] employed for testing and person-in-charge of testing.
- ⁶[(3) The approval, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of approval and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and ¹[***] Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.]

^{*} Delete whichever is not applicable.

4.	The	approv	al is s	subject	to the	condition	is stated	below	and	such	other
cond	itions	as may	be spe	ecified i	n the I	Rules for t	he time	being in	forc	e und	er the
Act.											

Date	Signature
	Designation

Conditions of Approval

- (1) This approval ²⁹³[**»] shall be kept in the approved premises and shall be produced at the request of the Inspector appointed under the Act.
- (2) If the approved institution wishes to undertake during the currency of the approval the testing of any other category of drugs ²⁹⁴[***] it should apply to the approving authority for necessary endorsement as provided in Rule 150B. This approval will be deemed to extend to the items so endorsed.
- (3) Any change in the analytical staff or in the person-in-charge of the testing shall be forthwith reported to the approving authority.
- ³[(4) The approved institution shall inform the approving authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the approving authority in the name of the institution with the changed constitution.]]

FORM 38 ²⁹⁵[***]

⁵[FORM 39

[See rule 150E(f)]

REPORT OF TEST OR ANALYSIS BY APPROVED INSTITUTION

(1) Name of manufacture from whom sample received together with his manufacturing licence number under the Act and under the rules made thereunder.

- (2) Reference number and date of the letter from the manufacturer under which the sample was forwarded.
 - (3) Date of receipt of the sample.
- (4) Name of $drug/\frac{296}{2}[***]$ /raw material purporting to be contained in the sample.
- (5) Details of raw material/final product (in bulk)/final product (in finished pack)* as obtained from the manufacturer:
 - (a) Original manufacturer's name in the case of raw materials and drugs repacked.
 - (b) Batch number.
 - (c) ²⁹⁷[Batch size as represented by sample.]
 - (d) Date of manufacture, if any
 - (e) Date of expiry, if any.
 - (6) Results of test or analysis with protocols of test analysis applied.

In the opinion of the undersigned, the sample referred to above is of standard quality/is not of standard quality as defined in the Act and the Rules made thereunder for the reasons given below.

Date.....Signature of person-in-charge of testing]

Note: Final product includes repacked material.

* Delete whichever is not applicable.

¹[FORM 39A

[See sub-rule (f) of rule 150E]

REPORT OF TEST OR ANALYSIS BY APPROVED INSTITUTION FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY

(1) Name of individual or organisation or procurement agency from whom sample is received
(2) Serial number and date of sender's memorandum
(3) Number of samples
(4) Date of receipt of the sample
(5) Name of drug or cosmetics or raw material purporting to be contained in the sample
(6) Details of raw material or final product in bulk or final product in finished pack' as obtained by sender:
(a) Name and address of the Manufacturer and Licence number mentioned on the label
(b) Name of original Manufacturer in the case of raw materials and repacked drugs
(c) Batch number
(d) Date of manufacture, if any
(e) Date of expiry, if any
(7) Results of test or analysis with protocols of test or analysis applied.
In the opinion of the undersigned, the sample referred to above is *o standard quality/is not of standard quality as defined in the Act and the rule made thereunder for the reasons given below.
DateSignature of Person-in-charge of testing

Note: Final product includes repacked material.

* Delete whichever is not applicable.]

²[FORM 40

(See rule 24A)

APPLICATION FOR ISSUE OF REGISTRATION CERTIFICATE FOR IMPORT OF DRUGS INTO INDIA UNDER THE DRUGS AND COSMETICS RULES, 1945

COSMETICS RULES, 1943
I/We*,(name and full address) hereby apply
for the grant of Registration Certificate to the manufacturer M/s
(full address with telephone, fax and E-mail address of the
foreign manufacturer) for his premises, and manufactured drugs meant for
import into India.
1. Name of Drugs for registration.
2. I/We* enclose herewith the information and undertakings specified in
Schedule $D(I)$ and Schedule $D(II)$ duly signed by the manufacturer for grant of
Registration Certificate for the premises stated below.
CDSCO CDSCO
3. A fee offor registration of premises, the particulars of which are given below, of the manufacturer has been credited to
the Government under the Head of Account "0210 Medical and Public Health.
04-Public Health, 104-Fees and Fines" under the Drugs Rules, 1945—Central
vide Challan No dated (attached in
original).
4. A fee offor registration of the drugs for import as specified at Serial No.2 above has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs Rules, 1945—Central <i>vide</i> Challan No
5. Particulars of premises to be registered where manufacture is carried on:
Address(es)
Telephone

Fax
E-mail
I/we undertake to comply with all the terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.
Place
Date Signature Designation Seal/Stamp of manufacturer or his authorised agent in India
Designation
Registration Certificate No
3. This Registration Certificate shall be in force from unless it is sooner suspended or cancelled under the rules.

- 5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Act and the rules, from time to time.

Place	Licensing Authority
Date	Seal/Stamp

Conditions of the Registration Certificate

- 1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
- 2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
- 3. The manufacturer of his authorised agent in India shall comply with the conditions of the importaicence issued under the Drugs Rules, 1945.
- 4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, *viz*. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The despatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course

of action, including the withdrawal of the drug from Indian market within 48 hours time period .

5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate.

In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub-rule (3) of rule 24A.

6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and/or address of the registered office/factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises.]

FORM 42

[***]

FORM 43

²[FORM 44

(See rules 122A, 122B, 122D and 122DA)

APPLICATION FOR GRANT OF PERMISSION TO IMPORT OR MANUFACTURE A NEW DRUG OR TO UNDERTAKE CLINICAL TRIAL

I/w	e	of M/s (address) hereby apply
mar	nufac	t of permission for import of and/or clinical trial or for approval to ture a new drug or fixed dose combination or subsequent permission dy approved new drug. The necessary information/data is given below:
1.	Parti	culars of new drug:
	(1)	Name of the drug:
	(2)	dosage form:
	(3)	Name of the drug: dosage form: Composition of the formulation: Test specification: CDSCO
	(4)	Test specification:
		(i) active ingredients:
		(ii) inactive ingredients सत्यमेव जयते
	(5)	Pharmacological classification of the drug:
	(6)	Indication for which proposed to be used:
	(7)	Manufacture of the raw material (bulk drug substances):
2.		submitted along with the application (as per Schedule Y with indexing e nos.)
A. I	Permi	ssion to market a new drug:
	(1)	Chemical and Pharmaceutical information
	(2)	Animal pharmacology

(3) Animal Toxicology

(4) Human/Clinical Pharmacology (Phase 1) (5) **Exploratory Clinical Trials (Phase II)** Confirmatory Clinical Trials (Phase III) (including published review articles) Bio-availability, dissolution and stability study Data (7) Regulatory status in other countries (8) (9) Marketing information: Proposed product monograph (a) Drafts of label and cartoons CONTROL (b) (10) Application for test license ¹[(11) New Chemical Entity and Global Clinical Trial Assessment of risk versus benefit to the patients (a) (b) Innovation vis-à-vis existing therapeutic option Unmet medical need in the cou (c) Subsequent approval/permission for manufacture of already approved new drug:— Formulation: (a) (1) Bio-availability/bio-equivalence protocol (2) Name of the investigator/centre (3) Source of raw material (bulk drug substances) and stability study data. Raw material (bulk drug substances) (b) Manufacturing method (1)

	(2) repo	Quality control parameters and or analytical specification, stability rt.
	(3)	Animal toxicity data.
C.	Appr	oval/permission for fixed dose combination:
	(1) journ	Therapeutic Justification. (authentic literature in ²⁹⁹ [peer-reviewed nals]/text books)
	(2)	Data on pharmacokinetics/pharmacodynamics combination.
	(3) effic	Any other data generated by the application on the safety and acy of the combination.
D.	Subs	equent approval or approval for new indication—new dosage form:
	(1)	Number and date of approval/permission already granted.
	(2)	Therapeutic Justification for new claim/modified dosage form.
	(3)	Data generated on safety or quality parameters.
		ee of rupees
beer	n c ount	redited to the government under the head of
Date	ed	Signature
		Designation
1	Note	—Delete, whichever is not applicable.

¹[FORM 45

(See rule 122A, 122D, 122DA)

PERMISSION TO IMPORT FINISHED FORMULATION OF A NEW DRUG

Nun	nber of the perm	ission a	nd date of	issue	•••••		
hereby		nport th	e followir	ng new dr		(address nulation under	
(1)	Name of the N	ew drug	:				
(2)	Dosage from:						
(3)	Composition:		STANDARD CO	CONTA			
(4)	Indication	ORUGS!		Of Of	o O		
Dated		184		Signatu	re		••••
		CDS	co	Name Licensir	and g Autho	Designation ority	of
	Conc	lition for	grant of a	pproval/pe नयते	rmissio	n	
		PLON			X		

- (1) The formulation shall confirm to the specification approved by the Licensing Authority.
- ²[(2) The proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.]
- (3) The label of the innermost container of the drug and every other covering in which the container is packed shall bear a ³[caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule HI or Schedule X, as specified in rule 97, in legible

black coloured font size in a completely red rectangular box] without disturbing the other condition printed on the label to depict it is prescription drug.

(4) The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

"WARNING: To be sold by the retail on the prescription of a.....only."

- ⁴[(5) As Post Marketing Surveillance, the applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.]
- (6) All reported adverse reaction related to the drug shall be intimated to the drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be complied with.
- (7) No claims except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.
- (8) Specimen of the cartoon, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drug is marketed.
- (9) Each consignment of imported drug shall be accompanied by a test/analyse report.

¹[FORM 45A

(See rules 122A and 122DA)

PERMISSION TO IMPORT RAW MATERIAL (NEW BULK DRUG SUBSTANCE)

Number of	the pern	nission a	and d	ate of issue	• • • • • • • • •	••••••	•••		
M/s				of				(add	dress)
hereby perm	itted to	import	the	following	raw	material	(new	bulk	drug
substances) u	nder ride	122A/12	22D <i>A</i>	A of the Dru	igs Ri	ales, 1945	, name	ly:—	

Name of the raw material (new bulk drug substances):

(1)
(2)
(3)
Dated
Conditions for Grant of Approval/Permission
(1) The raw material (new bulk drug substance) shall conform to the test specifications as approved by the Licensing Authority.
(2) For manufacture of raw material (new bulk drug substance) or it formulation in the country, separate approval under rule 122B shall be obtained from the Licensing Authority. (3) The permission to import shall not be used to convey or imply that the raw material (new bulk drug) is categorized as "life saving or essential drug".] CDSCO [FORM 46 DSCO (See rule 122B, 122D, 122DA). PERMISSION/APPROVAL FOR MANUFACTURE OF A NEW DRUG FORMULATION. Number of the permission and date of issue
M/s
(1) Name of the formulation:
(2) Dosage form:
(3) Composition:
(4) Indications:

Dated	Signature
-------	-----------

Name and Designation of Licensing Authority.

Conditions for grant of approval/permission

- (1) The formulation shall confirm to the specification approved by the Licensing Authority.
- ¹[(2) The proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written below or after the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.]
- (3) The label of the innermost container of the drug and every other covering in which the container is packed shall bear a ²[caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule HI or Schedule X, as specified in rule 97, in legible black coloured font size in a completely red rectangular box] without disturbing the other condition printed on the label to depict it is prescription drug.
- (4) The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

"WARNING: To be sold by the retail on the prescription of a.....only."

- ³[(5) As Post Marketing Surveillance, the applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.]
- (6) All reported adverse reaction related to the drug shall be intimated to the Drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be complied with.
- (7) No claims except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.

(8) Specimen of the cartoon, labels, package insert that will be adopted for marketing the drug in the country, shall be get approved from the Licensing Authority before the drug is marketed.

⁴[FORM 46A

(See rules 122B and 122DA)

PERMISSION/APPROVAL FOR MANUFACTURE OF RAW MATERIAL (NEW BULK DRUG SUBSTANCE)

Number	of	the	permission	and	date	of
issue	•••••	• • • • • • • • • • • • • • • • • • • •				
3.67			C	(11)		1 1
			f			_
granted Permis	ssion/App	roval to r	nanufacture the fo	ollowing raw	materi	al (new
bulk drug subs	tances) ur	nder rule 1	22B/122DA of th	e Drugs Rule	s, 1945	:
Name of the	e raw mat	erial (new	bulk drug substar	ice):		
(1)		3		NIZATION		
(1)(2)	CEA	····cdsco	CDSC			
(3)			ercutta जयते सत्यमेन जयते Signature ALTH, GOVERNI Name and D	MOIA		
Dated	•••••	PLON	सत्यमेन जुराते Signature	♂	•••••	
			ALTH, GOVERN			
			Name and D	esignation of	f the Li	censing
		A	uthority			

Conditions for Grant of Permission/Approval

- (1) The raw material (new bulk drug substance) shall confirm to the specifications approved by the Licensing Authority.
- (2) The raw material (new bulk drug substance) can be sold to only those manufacturers who have permission, in writing, from Licensing Authority, either to use the drug for development purpose/clinical trial/bio-equivalence study or to manufacture the formulation.

For manufacture of the formulation in the country, separate approval under rule 122B shall be obtained from the Licensing Authority.]

¹[FORM 47

(See rule 160 A)

APPLICATION FOR GRANT OR RENEWAL OF APPROVAL FOR CARRYING OUT TESTS ON AYURVEDIC, SIDDHA AND UNANI DRUGS OR RAW MATERIALS USED IN THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA AND UNANI DRUGS

- 1. *I/We..... of hereby apply for the grant/renewal of approval for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensee for manufacture for sale of Ayurvedic, Siddha and Unani drugs.
- 2. *Categories of Ayurvedic, Siddha and Unani drugs other than those specified in the First Schedule to this Act for which testing will be carried out:

AYURVEDA AND SIDDHASCO

- 1. Asava and Arista
- 2. Arka-Tinir

UNANI

- 1. Nabeez, Khal (Sirka)
- 2. Majoon and its sub-

TH, GOVERNICATE gories Itrifal, Jawarish, Khameera,

Laooq, Halwar

- 3. Sufoof, Zuroor, Sunoon.
- 4.Namak, Khar
- 5. Raughan
- 6. Zimad
- 7. Habb (Pill)
- 8. Shiyaf
- Qutoor(drops) 9.
- 10. Kohal (Surma), Kajal
- 11. Satt, Usara
- 12. Kushta
- 13. Joshanda (single drugs)
- 14. Sharbat Sikanjabeen

- 3. Avaleha and Paka-Ilakam
- 4. Kavatha Curna-Kutinir Curanam
- 5. Guggulu
- Ghrita-Nev 6.
- 7. Chuma-Curanam
- Taila-Tailam 8.
- 9. Dravaka-Tiravakam
- 10. Lavana-Uppu
- 11. Kshara-Saram
- 12. Lepa-Pacai
- 13. Vati, Gutika-Kulikai
- 14. Vartti

Sayyal, Arq (Distillates) 15. Netrabindu (Aschyotan) 15. 16. Anjana-Kanmai 16. Ours (Tablet) 17. Sattva-Sattu 17. Marham, Qairooti 18. Kupipakva Rasayana - Kuppi Centuram 18. Humool, Furzaja 19. 19. Parpati Bakhoor 20. Pishti 20. Nabati Advia 21. Bhasma-Parpam 21. Maadni Advia 22. Mandura-Atai Kutinir 22. Ajsad Advia 23. Rasayoga-Centuram 23. Haiwani Advia 24. Lauha 24. Jauhar 25. Ghana Sattva 25. **Natool** Nashooq, Naswar 26. Kvath Pravahi-Kutinir 26. 27. Panak (Syrup)-Manappaku 27. Shamoom 28. Tablet-Mattirai 28. Saoot (Nasal drops) 29. Capsule
30. Ointment-Kalimapu

28. Saoot (N

Mazoogh

31. Lashooq Mazoogh 30 Tila 31. 32. Gulgand Phalavarti 32. Dhoomravarti/Doopan Fateela 33. 33. Kshar Sutra/Kshar Varti 34. Ghaza, Ubtan, Sabhgh 34. Single drugs: CDSCO CDSCO (a) Plant based (b) Mineral based Metal based (c) (d) Animal based (e) Synthetic Any other Ayurvedic, Siddha, Unani (f) formulation. 35. Pushp (Phool) 35. Capsule 36. Huqna 36. Nasya 37. Naurah 37. Swarasa (Fresh juice) 38. Kama Bindu (Ear drops) 38. Latookh 39. Any other dosage form of Patent and 39. Vajoor (Throat pain)

40. Mazmazah (Mouth washer)

Proprietary and Ayurvedic, Siddha,

Unani Drug.

(3) Names, qualifications and experience of experts employed for testing and the person-in-charge of testing.
(4) List of testing equipment provided.
(5) *I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.
(6) An inspection fee of rupeeshas been credited to Government under the head of account
Dated
Signature
* Delete whichever is not applicable * Delete whichever is not applicable * [FORM 48] (See tule 160B) APPROVAL FOR CARRYING OUT TESTS OR ANALYSIS ON AYURVEDIC, SIDDHA AND UNANI DRUGS OR RAW MATERIALS USED IN THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA AND UNANI DRUGS
Number of approval and date of issue:
(1) Approval is hereby granted to
(2) Name of experts employed for testing and the person-in-charge of testing
(experts) and (person-in-charge)
(3) The approval shall be in force fromto

conditions as may be Act.	e specified in the rules for the time being in force under the
Date	Signature
Place	Designation
	Seal of State Licensing Authority
	Conditions of Approval

The approval is subject to the conditions stated below and such other

Conainons of Approvai

- This approval and any certificate of renewal in Form 42 shall be displayed in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.
- If the applicant wishes to undertake during the currency of the approval the testing of any other category of Avurvedic, Siddha or Unani drugs it should apply to the approving authority for necessary endorsement as provided in rule 160A. This approval will be deemed to extend to the items so endorsed.
- Any change in the experts or in the person-in-charge of the testing shall be forthwith reported to the approving authority.
- The applicant shall inform the approving authority in writing in the event of any change of the constitution of the laboratory operating under this Form. Where any change in the constitution of the laboratory takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the approving authority in the name of the laboratory with the changed constitution.]

¹[FORM 49

(See rule 160-1)

CERTIFICATE OF RENEWAL FOR CARRYING OUT TESTS OR ANALYSIS ON AYURVEDIC, SIDDHA OR UNANI DRUGS OR RAW MATERIALS USED IN THE MANUFACTURE THEREOF ON BEHALF OF LICENSEES FOR MANUFACTURE FOR SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

(1) Certified that approval number granted on the
day of 2001 for carrying out tests of identity, purity, quality
and strength on the following categories of Ayurvedic, Siddha or Unan
drugs and the raw materials used in the manufacture thereof at the
premises situated athas been renewed
fromto(Date).
CTANDARD CONTA
Categories of Ayurvedic, Siddha or Unani drugs
Categories of Ayurvedic, Siddha or Unani drugs
CDSCO CDSCO
(2) Names of experts and the person-in-charge of testing (experts
and(person-in-charge).
_ सत्यमेव जयते अर्थ
and
Place Designation
Trace
Seal of State Licensing Authority
¹ [FORM 50
[See rule 160 D(f)]
REPORT OF TEST OR ANALYSIS BY APPROVED LABORATORY
(1) Name of manufacturer from whom sample received together with his
manufacturing license number under the Act or the rules made
thereunder
(2) Reference number and date of the letter from the manufacturer under
which the same was forwarded

(3) Date of receipt of the sample						
(4) Name of Ayurvedic, Siddha and Unani drug or raw material purporting to be contained in the sample						
(5) Details of raw material of final product (in bulk finished pack)* as obtained from the manufacturer:						
(a) Original manufacturer's name in the case of raw materials and drugs repacked						
(b) Batch number						
(c) Batch size as represented by sample						
(c) Batch size as represented by sample						
(e) Date of expiry, if any						
(6) Results of test or analysis with protocols of test or analysis applied or as per Ayurvedic, Siddha or Unani Pharmacopoeial standards. (7) Other specific tests for identity, purity, quality and strength of Patent and Proprietary drugs. In the opinion of the undersigned, the sample referred to above is of standard Equality/is not of standards quality as defined in the Act or the rules made thereunder for the reasons given below:						
(Signature of the person-in-charge of testing)						
Date(F.No)						
Place						
Name and Address of the Laboratory						
Licence No						
Note.—Final product includes repacked material.						

"Delete whichever is not applicable.]

FORM 51

[See rules 71(9), 71A(5), 71B(v), 76(11) and 76A(v)]

FORM OF UNDERTAKING TO THE LICENSING AUTHORITY FOR MARKETING A DRUG UNDER A BRAND NAME OR TRADE NAME

(1) I of intend to market the drug specified below under a brand name or trade name—
(i) Name of the drug:
(ii) Dosage form:
 (iii) Composition: (2) I hereby give this undertaking that to the best of my knowledge based
on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and
internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.
name shall not lead to any confusion or deception in the market. Place
Date[Signature, Name, Designation
Seal/Stamp of manufacturer or on behalf of the manufacturer]]
[SCHEDULE B
(See rules 7 and 48)
FEES FOR TEST OR ANALYSIS BY THE CENTRAL DRUGS LABORATORIES OR STATE DRUGS LABORATORIES
1. Fees for test and assay of Drugs requiring use of animals—
Rupees
Adrenocorticotrophic hormone assay 1000

APPENDIX FORM COS- 1

[See rule 12(2), and 12(7)]

Application for issue of registration certificate for import of cosmetics into India

certificat fax and	te to the manufactur	er, M/ s _ the forei	(full d ign manu	address	r thegrant of registration with telephone number, r) for his manufactured
	ames of cosmetics a for registration.	along witl	h their br	and nar	me and pack size(s) and
Serial number	Product or brand of cosmetic	Brand name	Variant name	Pack sizes	Actual manufacturer and its premises
1.					
2.					
Part-I or registration 3. A at serial Head of and Fine dated	f Second Schedule for certificate for the form of the	duly sign premises for registres been creatical and latics Rules original).	gned by stated be ration of colited to the Public Hear, 2020 - C	the ma low:— osmetic e Centra alth, 04 entral v	andertaking specified in nufacturer for grant of es for import as specified al Government under the Public Health, 104-Fees wide Challan No,
4. I	Particulars of premis	es to be re	egistered v	where m	nanufacture is carried on:
Address	(s):_				
Telephoi	ne :				
Fax:_					

E-mail :
we undertake to comply with all the terms and conditions required to obtain registration certificate and to keep it valid during its validity period.
Place:
Date:
Signature_
Name
Designation

Seal/Stamp of manufacturer or his Authorised agent in India.

(**Note:** In case the applicant is an Authorised agent of the manufacturer in India, an undertaking for the purpose of registration is to be enclosed as per Part-I of Second Schedule)

FORM COS-2

[See rule 13(1) and 13(4)]

Import registration certificate to be issued for import of cosmetics into India

Registration Certificate No.____ Date___M/s_(Name and full address of registered office) having factory premises at_(full address) has been registered under rule 13 as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of cosmetics, along with their brand names and pack size(s) and variants which may be imported under this registration certificate.

Serial	Product or brand of	Brand	Variant	Pack	Actual	
number	cosmetic	name	name	sizes	manufacturer and its premises	3
1.						

2.			

- 3. This registration certificate shall be in force from_to __unless it issooner suspended or cancelled under the rules.
- 4. This registration certificate is issued through the office of manufacturer or his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer, namely M/s.....(name and full address)......who shall be responsible for the business activities of the manufacturer, in India in all respects.
- 5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time in this regard.

Place	• •••••	• • • • • • •	•••••
Date:			

CENTRAL LICENSING AUTHORITY

Seal / Stamp

Conditions of the registration certificate

- 1. The registration certificate shall be produced by the authorised importer or distributer or agent as and when required by the Licensing Authority or regulatory authority.
- 2. The manufacturer or his authorised importer/distributor/agent in India shall inform the Licensing Authority forthwith in the event of any administrative action taken namely, market withdrawal, regulatory restrictions, or cancellation of authorisation, and not of standard quality report of any cosmetic pertaining to this registration certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed/sold or distributed.

The dispatch and marketing of the cosmetic in such cases shall be stopped and the Licensing Authority shall be informed immediately. Further action in respect of such stopped marketing of cosmetic shall be followed as per the direction of the Licensing Authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the Licensing Authority. The Licensing Authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.

- 3. The manufacturer or his authorised agent or importer or distributor or subsidiary in India shall inform the Licensing Authority within thirty days, in writing, in the event of change in labelling or composition or testing, or specification or in documentation of any of the cosmetic pertaining to this Registration Certificate along with an undertaking that the products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.
- 4. The manufacturer or his authorised agent in India shall inform the Licensing Authority immediately in writing, in the event, of any change in the constitution of the firm operating under this registration certificate. Where any such change in the constitution of the firm takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of one hundred and eighty days from the date on which the change has taken place unless, in the meantime, a fresh registration certificate has been taken from the Licensing Authority in the name of the firm with the changed constitution of the firm.
- 5. In case of change in name or address of a registration holder or overseas manufacturer, operating under this registration certificate, an application for amendment shall be made in online portal of Central Government for prior approval from the Central Licensing Authority for the said changes in registration certificate within a period of sixty days from the date of such change.
- 6. The importer shall notify to the Licensing Authority immediately in writing, on the class of the cosmetic product which present a risk to the human health and the corrective measure taken.

[See rule 13(3), 23(3), 32(2) and 32(3)]

Permission to import or manufacture new cosmetics in India

Number of the permission and date of issueM/s
having addressis hereby permitted to import or manufacture the
following new cosmetic under rule 32 of the Cosmetics Rules, 2020.
1. Name of the cosmetic
2. Category or intended use
3. Composition of the product
4. Any special instruction
Dated:
Signature

Name and Designation of Central Licensing Authority:

Conditions for the grant of permission to import or manufacture new cosmetic

- 1. The cosmetic product shall conform to the specifications as permitted by the Central Licensing Authority
- 2. Name of the cosmetic shall be printed or written in indelible ink and shall appear in a conspicuous manner.
- 3. Any special instructions as permitted shall be printed on the label.
- 4. No claims other than those permitted shall be made on the label without the prior approval of the Central Licensing Authority

[See rule 17(11))]

Application for issue of Import Registration Number for Import of already registered cosmetics.

I/We*_	_(Name	and	full	address	of	importer)hereb	by apply	for	the	grant	of
registrat	tion num	iber f	or In	nport of a	lrea	ady registered c	cosmetics,	, me	ant f	or imp	ort
into Ind	ia.										

1. Detail of cosmetics

Serial number	Name of cosmetic	(Name of manufacturer and address)	Pack sizes	Registration Certificate Number
1.				1 (0.11.50)
2.				
3.				

- 2. I/We* enclose herewith the information and undertaking specified in Sixth Schedule duly signed.
- 3. I/we undertake to comply with all the terms and conditions required to obtain registration number and to keep it valid during its validity period.

Address(s):_	
Telephone :_	
Fax:_	
E-mail :	
Place:	
Date:	
	Signature_
	Name_
	Designation

FORM COS-4A

[See rule 17(2)]

Import Registration Number to be issued for import of already registered cosmetics into India

Import l	Registration No.:		Date	
17 as a import of	,	reby issued	porter)has been register this Import Registration India.	
Serial number	Name of cosmetic(s)	Pack size(s)	Name and address of m	anufacturer
1. 2.				
unless it 4. below a	t is sooner suspended This Import Registra	or cancelled attion Number litions as may	er shall remain valid for under the Cosmetics Ru er is subject to the cor by be specified in the rule 2020.	les, 2020.
Place:	_			
Date:_				
			Central Licen	sing Authority
				Seal / Stamp

Conditions of the Import Registration Number

1. This Import Registration Number shall be produced by the importer as and when required by the Licensing Authority or regulatory authority.

- 2. The importer shall inform to the Licensing Authority forthwith in the event of any administrative action taken namely, market withdrawal, deletion of product from the original Registration Certificate holder's or any regulatory restrictions of any cosmetics pertaining to this registration.
- 3. The importer shall provide the statement of details of cosmetics imported by them annually to the Central Licensing Authority.

[See rule 23(2)]

Application for grant of a license to manufacture cosmetics for sale or for distribution

	1.	I/We	••••	• • • • • • • • • • • • • • • • • • • •	of		• • • • • • • • • • • • • • • • • • • •	hereby	apply	for t	he	grant
of	a	License	to	manufacture	on	the	premises	situated	at	• • • • • • • •	•••••	. the
fol	lov	wing cosn	neti	cs:								

2. Details of cosmetic products:

Number cosmetic ingredients Grade of	Function of ingredients
ingredients	edients

- 3. Names, qualifications and experience of technical staff employed for manufacture and testing.....
- 4. A fee of rupees......has been credited to Government under the

head of account.....

Date.....

Signature.....

Note: The application should be accompanied by a plan of the premises.

[See rule 23(2)]

Application for grant of a loan license to manufacture cosmetics for sale or for distribution

license to manufacture cosmetics, for sale, on the Premises situated at

1. I/Wehereby apply for grant of a loan

	C/o	the foll	owing cosmetics:				
2. Details	of cosmeti	ic products:					
Serial Number	Name of cosmetic	Name of ingredients	Specifications or Standards or Grade of ingredients	Percentage of Ingredients	Function of ingredients		
3. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.							
4. I/We enclose(a) A true copy of a letter from me/us to the manufacturing concern whose							
		•	d to be utilized by m				
(b) A true copy of a letter from - the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me / us and they will analyse every batch of and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.							
(c) manufact	_	s of labels,	cartons of the pa	roducts pro	posed to be		
	fee of rupe		has been credited	to Governm	ent under the		
Date		•••••					

Signature	• • •	••
-----------	-------	----

Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also their license number.

FORM COS-7

[See rule 23(4) and 23(7)]

Self-certificate of compliance of Good Manufacturing Practices (GMP) for manufacture of cosmetics

(To be given by the applicant along with Form COS- 5 or Form COS- 6 at the time of application for manufacturing licence or loan licence)

ume of application to	r manuracturing neen	ce or ioan neence)	
1. I/Weof a License	of	hereby applie	d for the grant
i:o manufacture at pre	emises situated at	the following c	osmetics.
1			
2			
3			

- 2.1/We hereby declare that the above premises having facilities of good manufacturing practices, requirements of premises, plants and equipment for manufacture of above cosmetics as per the Seventh Schedule of the Cosmetics Rules, 2020.
- 3. I/We undertake to provide facility to inspect the above premises as per the Cosmetics Rules, 2020 to the State Licensing Authority or any officer appointed by the authority.
- 4. I/We undertake that in case State Licensing Authority or any officer appointed by the authority found any deficiency during an inspection the State Licensing Authority have a full right to cancel or give any direction for improvement for Good

Serial Number	Name of cosmetic	Name of ingredients	Standards or	of Ingredients	Function of ingredients
			Specifications or	Percentage	
(a) Details	s of cosmet	tic products:			
premises	situated at.		hereby licensed the following cosm		
Lice			of issue		don Number
Lio			26(g), 27(1), 28 and smetics for sale or		tion Number
		F	ORM COS- 8		
					Designation:
					Signature:
					Name:
Place:					
Date:					
Licensing	Authority	in this regard			
cosmetics	. Further I	will not clain	n any damages, etc.	for any action	on of the State

Manufacturing Practice in the said premises in respect of the above said

- (b) Names of the technical staff.....
- 2. The licence unless sooner suspended or cancelled shall continue to remain valid. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act and Rules shall be assessed at least once in a year.
- 3. The license is subject to the conditions stated below and to such other conditions as may be specified in the Cosmetics Rules, 2020.

State Licensing Authority Signature..... Designation..... Date of issue..... **Conditions of License** This license shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940. Any change in the technical staff shall be forthwith reported to the Licensing Authority. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for the necessary endorsement to the license as provided in rule 23. This license shall be deemed to extend to the cosmetics so endorsed. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of six-months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution. FORM COS-9 [See rule 25, 26(g), 27(1), 27(3), 28 and 30(1)] Loan license to manufacture cosmetics for sale or for distribution

situated

premises

following

manufacture

the

1. Number of license and date of issue.....

2...... here by granted a loan license to

the

on

cosmetics

			under the	direction a	and personal		
supervision of the following technical staff: a. Names of the technical staff							
b. Details of cosmetic products							
Serial Number	Name of cosmetic	Name of ingredients	Specifications or Standards or Grade of ingredients	Percentage of Ingredients	Function of ingredients		
 The licence unless sooner suspended or cancelled shall continue to remain valid. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act and Rules shall be assessed at least once in a year. The license is subject to the conditions stated below and to such other conditions as are specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940. 							
State Licensing Authority							
Date							
				Signatu	ıre		
				Design	nation		
Conditions of Licence							

- 1. The license shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.
- 3. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for necessary endorsement to the license as

provided in rule 23. This license shall be deemed to extend to the cosmetics so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of six months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM COS-10

[See rule 26(i) and 44(1)]

Intimation to person from whom sample is taken

I have this day taken from the premises of.	situated at
samples of the cosmetics specanalysis.	ified below for the purpose of test or
Date	Inspector
Details of samples taken	
Date	Inspector
FORM CO	OS- 11
[See rule 26(k)	and 62(i)]
Form in which the inspection	book shall be maintained
A. The cover of the Inspection Book shamely:	all contain the following particulars,
1. The name and address of the lice	ensee
2. License number and the date	e up to which the license is valid

stamped by the Licensing Authority. The pages, other than the first and the last pages, shall have the following particulars:-
Name and designation of the Inspector who inspects the premises of the licensee:—
Date of Inspection
Observations of the Inspector
Signature of the Inspector
(ii) The first and last pages of the Inspection Book shall be endorsed by the Licensing Authority with the following word, namely:-
'Inspection Book maintained by M/ssituated atfor license numberin Formunder the Cosmetics Rules, 2020.
Seal and signature of the Licensing Authority.
Notes:
(i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment.
(ii) The Inspection Book shall be maintained at the premises of the licensee.
(iii) The observations made by the Inspector shall be in triplicate. The original copy shall be retained in the inspection Book to be maintained in the premises of the licensee. The duplicate copy shall be sent to the Licensing Authority. The

(i) The pages of the Inspection Book shall be serially numbered and duly

B.

triplicate copy shall be taken as record by the Inspector.

[See rule 32(1)]

Application for grant of permission for new cosmetics for obtaining import registration certificate or manufacturing license

I/We*_(*Name and full address*) hereby

apply for the grant of permission to import or manufacture a new cosmetics in India. The necessary information or data is given below:—

- 1. Particulars of new cosmetic:—
- a. Name of the cosmetic
- b. Category of cosmetic/intended use
- c. Composition of the product
- d. Test protocols/specification of the raw materials and finished product
- 2. Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure
- 3. Existing data on undesirable effects on human health resulting from use of the cosmetic product
- 4. Supporting data for the claimed benefits of cosmetic products should be made available to justify the nature of its effect
- 5. Draft of the product label and carton
- 6. Whether the product is marketed in any other country; list thereto
- 7. Any other data generated on safety, efficacy and quality parameters
- 8. A total fees of USD......(in words)......has been credited to the Government under the head of account......(photocopy of receipt is enclosed)

Signature of the Manufacturer/Importer/Authorised age	Signature of	the Ma	anufacturer/	Importer/	'Authorised	agent
---	--------------	--------	--------------	-----------	-------------	-------

Name:
Designation:
Stamp/Seal
Place:
Date: .
FORM COS- 13 [See rule 40] Application from a purchaser for test or analysis of a cosmetic under Section 26 of the Drugs and Cosmetics Act, 1940
 Full name and address of the applicant Occupation
3. Name of cosmetic purporting to be contained in the sample
4. Name and full address of the concern where the cosmetic was purchased
5. Date on which purchased
6. Reasons why the cosmetic is being submitted for test or analysis
A fee ofhas been credited to Government under the Head of Account
"02.10- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the
Drugs and Cosmetic Rules 1945, - Central <i>vide</i> Challan Nodated
(attached in original)

or for me. I further declare that the sample of the cosmetic being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way. Date:..... Signed..... FORM COS- 14 [See rule 40] Report of test or analysis by Government Analyst under Section 26 of the **Drugs and Cosmetics Act, 1940** Name of person from whom sample received..... 2. Date of receipt..... 3. purporting to be Name of cosmetic contained in the sample..... Opinion of the Government Analyst—The sample referred to above is/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder. Date :.... Government Analyst..... FORM COS-15 (See rule 42) Receipt for stock of cosmetics for record, register, document or material object seized under section 22 (1) (c) or (cc) of the Drugs and Cosmetics Act, 1940 The stock of cosmetics for records, registers, documents or material objects detailed below has / have this day been seized by me under the provisions of clause (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act. 1940 (23 of 1940) from the premises ofsituated at Date..... Inspector.....

I hereby declare that the cosmetic being submitted for test was purchased by

Details of cosmetics, records, registers,	documents or material objects seized.
Date	Inspector
	COS- 16 le 44(2)]
under sub - section (1) of section 23 of	ken where fair price tendered thereof f the Drags and Cosmetics Act, 1940 is used
То	
	O, have taken from the premises amples of cosmetics as specified below:-
Details of Samples	
And whereas I had offered to pay you the samples of cosmetics taken:	rupees as the fair price of
And whereas, you have refused to accep	ot the fair price tendered thereof.
Now, therefore, I give you the rec samples of the cosmetics- taken by me.	ceipt as the fair price tendered for the
Date	Inspector
	COS- 17 le 45(1)]
Memorandum to G Serial No. of Memorandum	Sovernment Analyst
Scriai No. of Mchorandum	
From:	
То	
The Government Analyst,	

The portion of sample or container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of Section 23 of the Drugs and Cosmetics Act, 1940.

The portion of sample/'container has been marked by me with the following mark.

Details of portion of sample or container with name of cosmetic which it purports to contain— Date..... Inspector..... FORM COS- 18 (See rule 46) Order under section 22 (l)(c) of the Drugs and Cosmetics Act, 1940 requiring a person not to dispose of stock in his possession Whereas, I have reasons to believe that the stocks of cosmetics in your possession, detailed below contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940; Now, therefore, I hereby require you under clause (c) of sub-section (1) of section 22 of the said Act not to dispose of the said stock for a period of.....days from the date of this order. Inspector. Date..... Details of stock of cosmetics

Inspector.

Date.....

[See rule 48]

Report of tests or analysis of cosmetics by the Government Analyst.

1.	Name of the officer or Inspector from whom received	
2. mei	Serial number and date of the Officer's/Inspector morandum	's
3.	Number of sample	
4.	Date of receipt	
5. sam	Name of the cosmetic purporting to be contained in the ple	e
6.	Condition of seals on the packet or on portion of sample or container	
7.	Results of test or analysis:—	
The	e sample of cosmetics—	
(a)	contain a prescribed colour only or does not contain a prescribed colour.	
(b)	does not contain harmful ingredients or contains harmful ingredients.	
	conforms to claims made on the label as to the nature and quality of or some some some some some some some some	
and	contains not more thanparts per million of leaparts per million of Arseniparts per million of Arseniparts per million of Arsenic.	ic
Dat	e Government Analyst.	

[See rule 49(1) and 49(3)]

Memorandum to the Director, Central Cosmetic Laboratory

Sei	rial Number			
То	the	Director,	Central	Cosmetic
Labor	atory			
From.				
1 sen	d herewith, under t etics	he provisions of s	section 25 (4) of	the Drugs and
	940, sample(s) of a sis and	cosmetic purporti	ing to be	for test or
reques Court.	st that a report of the	e result of the test of	or analysis may be	supplied to this
2.	The distinguishing	number on the pack	cet is	
3.	Particulars of offen	ce alleged		
4.	Matter on which op	oinion is required		
5.	A fee of Rs	has been deposit	ed in Court.	
Date				
Magis	strate			

(See rule 51)

Report of test or analysis by the Central cosmetic laboratory

Certified	that	the	sample	bea	arıng		number
•••••		•••••	purporting	to	be	a	sample
of		rec	eived on	•••••	.with	mem	orandum
No			dated				
fromof such test or ar				analyse	ed and	that	the result
2. The conditi	on of the s	eals on the	packet on rece	ipt was	as fol	lows:	:
*3. In the opi of standard qual thereunder for th	ity as defin	ned in the I				-	•
Director,							
Date Ce	ntral cosm	etic laborat	ory or other au	thorize	d offic	er	
Details of res	ults of test	or analysis	with protocols	of test	applie	ed	
Director,							
Date C	entral cosn	netic labora	tory or other a	uthorize	ed offi	cer	
*If opinion is amended.	required of	on any othe	r matter, the pa	aragrap	h shou	ıld be	suitably
		FORM	I COS- 22				
		[See r	ule 55(1)]				
Application for	grant of a	pproval fo	r carrying out	t tests o	n cos	metic	s or raw
materials u			re thereof on or sale of cosm		of lice	ensees	s for
1. *I/We	•••••	of	£	he	reby a	apply	for the

grant of approval for carrying out tests on the following items of cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of cosmetics.

	2.	Items of cosmetics:
	(1)	
	(2)	•••••••••••••••••••••••••••••••••••••••
	(3)	
an		Name, qualifications and experience of expert staff employed for testing person-in-charge of testing.
	4.	List of testing equipments provided.
are		I/We enclose a plan of the testing premises showing the location and the different sections thereof.
(in	6.	An application fee of rupees or an inspection fee of
		application after rejection) of rupees has redited
to	Gov	ernment under the Head of Account
Da	ıte	Signature
		FORM COS- 23
		(See rule 56(1), 56(2), 58(1), 59, 60(1) and 62)
	App	roval for carrying out tests on cosmetics and raw materials used in
	the	eir manufacture on behalf of licensees for manufacture for sale of
		cosmetics
	1.	Number of approval and date of issue:
cai		Approval is hereby granted tofor g out tests for identity, purity and quality on the following items of

tuated
Items of cosmetics
(1)
(2)
(3)
3. Names of competent technical staff employed for testing and the erson-in-charge of testing.
4. The approval shall be in force fromto
5. The approval is subject to the conditions stated below and such other onditions as may be specified in the rules for the time being in force under the ct.
ateSignature
State Licensing Authority

Conditions of Approval

- 1. This approval shall be kept in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.
- 2. If the approved institution wishes to undertake during the currency of the approval the testing of any other items of cosmetics it should apply to the State Licensing Authority for necessary endorsement as provided in rule 56. This approval will be deemed to extend to the item so endorsed.
- 3. Any change in the analytical staff or in the person-in-charge of the testing shall be forth with reported to the State Licensing Authority.
- 4. The approved institution shall inform the State Licensing Authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval shall be deemed to be valid for a maximum period of

three months from the date on which the change takes place unless in the mean time, a fresh approval has been taken from the State Licensing Authority in the name of the institution with the changed constitution.

FORM COS-24

[See rule 62(f)]

Report of test or analysis by approved institution

- 1. Name of manufacturer from whom sample received together with his manufacturing licence number under the Act and under the rules made thereunder.
- 2. Reference number and date of the letter from the manufacturer under which the sample was forwarded
 - 3. Date of receipt of the sample.
- 4. Name of cosmetic/raw material purporting to be contained in the sample.
- 5. Details of raw material/final product in bulk/final product (in finished pack) as obtained from the manufacturer:
 - (a) Original manufacturer's name in the case of raw materials repacked.
 - (b) Batch number.
 - (c) Batch size as represented by sample.
 - (d) Date of manufacture, if any.
 - (e) Date of expiry, if any.
 - 6. Results of test or analysis with protocols of test or analysis applied.

In the opinion of the undersigned, the sample referred to above is *of standard quality/ is 7iot of standard quality* as defined in the Act and the rules made thereunder for the reasons given below.

Date.... Signature of Person-in-charge of testing Note-Final product includes repacked material.

REFERENCE

<u>1</u> *Vide* G.S.R. 763E), dated 15th Dec., 2020, published in the Gazette of India, Extra., Pt. II, Sec. 3(i), No. 632, dated 15th Dec., 2020.

31.	Defibrillators (effective from 1, April, 2021)
32.	PET Equipment (effective from 1, April, 2021)
33.	X-Ray Machine (effective from 1, April, 2021)
34.	Dialysis Machine (effective from 1, April, 2021)
35.	Bone marrow cell separator (effective from 1, April, 2021)
36.	Disinfectants and insecticide specified in Medical Devices Rules, 2017
37.	Ultrasound equipment (effective from 1, November, 2020)]

APPENDIX FORM MD-1

[Refer sub-rule (5) of rule 13]

APPLICATION FOR GRANT OF CERTIFICATE OF A NO AND CONT REGISTRATION OF A NOTIFIED BODY

- Name of applicant:
- Nature and constitution of Body 2.
- (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- Corporate / registered office address including telephone number, mobile number, fax number and e-mail id:त्यमेव जयते
- Details of accreditation (self-attested copy of certificate to be attached):
- Standards (BIS/ISO/Others) for which notified body has been accredited under rule 13:
- Fee paid on......Rs....receipt/challan/transaction id.....
- Documents enclosed, as specified in the Part I of the Third Schedule of the Medical Devices Rules, 2017, duly signed by me.
- 8. I undertake to comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017 and other terms and conditions for working as a Notified Body as may be specified from time to time.

Place:	
Date:	Signature of designated person in India (Name and designation) [To be signed digitally]
FORM	/I MD-2
[Refer sub-rul	e (6) of rule 13]
CERTIFICATE OF REGISTRA	ATION FOR A NOTIFIED BODY
UNDER THE MEDICAL	L DEVICES RULES, 2017
Registration No.:	
at (full address averagistered as a Notified Body of follo and non-measuring)] and/or Class B m 2. Details of Medical device(s):	(Name of the firm) situated with telephone and e-mail) has been wing Class A ⁵⁶ [(other than non-sterile dedical devices.
3. This Registration is subject to the c	onditions as specified in the Drugs and
Cosmetics Act, 1940 (23 of 1940) and	the Medical Devices Rules, 2017.
Place:	Central Licensing Authority
Date:	[To be signed digitally]
FORM	MMD-3

[Refer sub-rule (2) of rule 20]

APPLICATION FOR GRANT OF LICENCE TO MANUFACTURE FOR SALE AND DISTRIBUTION OF CLASS A ⁵⁷[(OTHER THAN NON-STERILE AND NON-MEASURING)] OR CLASS B MEDICAL DEVICE

- 1. Name of applicant:
- 2. Nature and constitution of manufacturer:

- (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 3. (i) Corporate /registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
- (iii) Address for correspondence: [corporate/registered office/manufacturing site]
- 4. Details of medical device(s) to be manufactured [Annexed]:
- 5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)
- 7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

CDSCO

- 8. I hereby state and undertake that:
- (i) the manufacturing site is ready for audit or shall be ready for audit on......in accordance with the requirements of Medical Devices Rules, 2017.
- (ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: Signature

Date: (Name and designation)

[To be signed digitally]

ANNEXURE

SI. No.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life		Brand Name (if registered
------------	-----------------	--------------	-----------------	-------------------------------	--------------------------	-----------------------	---------------	--	---------------------------------

				sterile	under the Trade
					Trade
					Marks Act, 1999)
					1999)

[Refer sub-rule (2) of rule 20]

APPLICATION FOR GRANT OF LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS A 58[(OTHER THAN NON-STERILE AND NON-MEASURING)] OR CLASS R MEDICAL DEVICE.

4	58[(OTHER THAN NON-STERILE AND NON-MEASURING)] OR								
	CLASS B MEDICAL DEVICE								
1.	Name of applicant:								

- 2. Nature and constitution of manufacturer: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 3. (i) Corporate / registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Name and address of manufacturing site including telephone number, mobile number, fax number and e-mail id:
- (iii) Address for correspondence: [corporate/registered office/manufacturing site]
- 4. Details of medical device(s) to be manufactured [Annexed]:
- 5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)
- 6. Fee paid on......Rs....receipt/ challan/ transaction id.....
- 7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
- 8. I hereby state and undertake that:

					rovisions of al Devices R			l Cosn	netics Act,
Pla	ce:	•••••	•••••	•••••		9	Signa	ture	
Dat	te:				···	(Name	and o	design	ation)
						[To	be sig	ned di	gitally]
				\boldsymbol{A}	NNEXURE	7			
SI. No.	Generic name	Model No.	Intended use	Class of medical device	Material of	Dimension (if any)	Shelf life	Sterile or Non- sterile	Brand Name (if registered under the Trade Marks Act. 1999)
			Ö	CDSCO	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	DSCO			
]	L DISTR	ICEN IBUTI	CE TO	(4) of r MANU CLASS	ORM MD: ule 20 and s FACTURE S A ⁵⁹ [(OTH	FOR SAI	LE O N NC	R FOI	R ERILE
Lic	ence Nu	ımber:	•••••	•••••					
ma: dev	nufactui nufactui vice(s) a	rer wire for t the p	ith tele _l sale or remises	phone, for di situated	(Nata and existribution at	e-mail) ha	as be clow	een li liste (censed to d medical (address of
2.	Details	s of me	edical de	vice(s) [Annexed],				

2017 and conditions prescribed therein.

3. This licence is subject to the provisions of the Medical Devices Rules,

Pla	ce:	•••••	•••••	••••	State Licensing Authority					
Dat	te:	•••••	•••••			[To be signed digitally]				
	ANNEXURE									
SI. Generic Model Intended No. Intended No. Intended device Class of medical device Material of Construction (if any) Shelf Non-sterile						Brand Name (if registered under the Trade Marks Act, 1999)				
Loa 1. add	LOAD DISTRIAND an Licen M/s dress of nufacture	N LICIBUTI NON- nce Nu manuf	CENCE ON OF MEASU mber: Cacturer versale or for	(4) of reconstruction	ORM MD- ule 20 and s NUFACTU A 1 (OTE OR CLAS ophone, fax bution the b	RE FOR ER THAT ES B MEE CDSCO and e-mail	SALIN NO DICA (a) has d med	E OR DN-ST L DEV	FOR ERILE VICE and full licensed to evice(s) at	
(ad out	dress of along v	f manu with th	ıfacturin	g facilit e numbe	ty where the cr) C/o	e manufac	turing	g will	be carried	
2.	Details	s of me	edical de	vice(s) [Annexed].					
3. 201			is subje ons presc		e provisions erein.	of the M	edica	ıl Devi	ces Rules,	
Pla	ce:	•••••	•••••		••••	State Lice	ensing	g Autho	ority	
Date: [To be signed digitally]							tally]			

ANNEXURE

SI. No.	Generic name	Model No.	Intended use	modiaal	Material of construction	Shelf life	Sterile or Non- sterile	Brand Name (if registered under the Trade Marks Act, 1999)

FORM MD-7

[Refer sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

APPLICATION FOR GRANT OF LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D

- FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D

 1. Name of applicant:
- 2. Nature and constitution of manufacturer:
- (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
- (iii) Address for correspondence: [corporate/registered office/manufacturing site]
- 4. Details of medical device(s) to be manufactured [Annexed]:
- 5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)
- 6. Fee paid on......Rs....receipt / challan / transaction id.....

- 7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
- 8. I hereby state and undertake that:
- (i) the manufacturing site is ready for audit or shall be ready for audit on......in accordance with the requirements of Medical Devices Rules, 2017.
- (ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:	Signature	Signature		
Date:		(Name and de	esignation)	
[To be signed digitally]	EUCS STANDARD CONTRO	ORGANIZ		
SI. Generic Model Intended No. name No. use	Class of Material of Di	Sterile mension Shelf or life Non- sterile	Brand Name (if registered under the Trade Marks Act, 1999)	

[Refer sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

APPLICATION FOR GRANT OF LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D

- 1. Name of applicant:
- 2. Nature and constitution of manufacturer:

- (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
- (iii) Address for correspondence:

[Corporate office/manufacturing site]

- 4. Details of medical device(s) to be manufactured [Annexed]:
- Fee paid on Rs. Rs. I have 5. Whether substantial equivalence to a predicate device is claimed: (Yes/No)
- receipt/challan/transaction id......
- I have enclosed the documents as specified in the Fourth Schedule of 7. Medical Devices Rules, 2017. CDSCO
- I hereby state and undertake that:
- the manufacturing site is ready for audit or shall be ready for audit (i) on.....in accordance with the requirements of the Medical Devices Rules, 2017.
- I shall comply with all the provisions of the Drugs and Cosmetics Act, (ii) 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Signature Place:

(Name and designation) Date:

[To be signed digitally]

ANNEXURE

SI.	Generic	Model	Intended	Class of	Material of	Dimension	Shelf	Sterile	Brand
No.	name	No.	use	medical	construction	(if any)	life	or	Name (if

		device		Non-	registered under the
				sterile	under the
					Trade
					Marks Act, 1999)
					1999)

[Refer sub-rule (1) of rule 25]

LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D

Lic	ence Nu	ımber:	•••••						
man the man 2. 3. resp dev 4.	preminufactur Details The nationsible ice(s).	re for sises ring factors s of meaning, go e for the	sale or for situated cility where dical dequalification manufactures are manufactured in the subject of the sub	at a	phone, fax and pution the below manufacturing values of the testing of the provisions of the provision	w listed move in the above r	edical ried or tent to	l devic (addre ut). echnica	e(s) at ss of al staff nedical
						ntral Licen [To be s	•		•
SI. No.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non- sterile	Brand Name (if registered under the Trade Marks Act, 1999)

[Refer sub-rule (1) of rule 25]

LOAN LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF CLASS C OR CLASS D MEDICAL DEVICE

Loan Licence Number:	
1. M /s	(Name and full
address of manufacturer with telephone, fax and e	e-mail) has been licensed to
manufacture for sale or for distribution the below	listed medical device(s) at
the premises situated at	(address of
manufacturing facility where the manufacturing w	ill be carried out along with
the licence number) C/o	(name of
manufacturing site licence holder).	
2. Details of medical device(s) [Amexed] Wire of the control of th	
3. The names, qualifications and experience o	f competent technical staff
responsible for the manufacture and testing of the	e above mentioned medical
device.	ATION
4. This licence is subject to the provisions of t	he Medical Devices Rules,
2017 and conditions prescribed therein.	MON
Place: सत्यमेव जयते 🦽	State Licensing Authority
Place: सत्यमेव जयते Date: AEALTH, GOVERNMENT	-
Date:	[To be signed digitally]

ANNEXURE

SI. No.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non- sterile	Brand Name register under Trade Marks 1999)	(if red the Act,

[Refer clause (vii) of rule 26]

FORM IN WHICH THE AUDIT OR INSPECTION BOOK SHALL BE MAINTAINED

(A) The cover of the audit or inspection book shall contain the following particulars, namely:—
1. The name and address of the licensee
2. Licence Number
(B) (i) The pages of the audit or inspection book shall be serially numbered and duly stamped by the Central Licensing Authority* / State Licensing Authority*. The pages, other than the first and the last pages, shall have the
following particulars:—
Name and designation of the auditor or medical device officer who audited or inspected the premises:
Date of audit or inspection:
Observations of the auditor or medical device officer: Signature of the auditor or medical device officer
(ii) The first and last pages of the audit or inspection book shall be endorsed by the Central Licensing Authority State Licensing Authority* with the following words, namely:—
Audit or inspection book maintained by M/ssituated at in Formfor licence number under the Medical Devices Rules, 2017.
*"Central Licensing Authority/
*State Licensing Authority
[To be signed digitally]
*Delete whichever is not applicable.
Notes:

- (i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time to time.
- (ii) The audit or inspection book shall be maintained at the premises of the licensee.
- (iii) The original copy of observations made by the auditor or medical device officer shall be maintained in the premises of the licensee and duplicate copy shall be sent to the Central Licensing Authority/State Licensing Authority. The triplicate copy shall be taken as record by the auditor or medical device officer.

[Refer sub-rule (1) of rule 31]

APPLICATION FOR LICENCE TO MANUFACTURE MEDICAL DEVICE FOR PURPOSE OF CLINICAL INVESTIGATIONS, TEST, EVALUATION, EXAMINATION, DEMONSTRATION OR

TRAINING

1. Name of applicant:

CDSCO J

CDSCO

- 2. Nature and constitution of manufacturer: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 3. (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Testing or evaluation site address including telephone number, mobile number, fax number and e-mail id:
- (iii) Address for correspondence: [corporate office / testing site]
- 4. Details of medical device(s) to be manufactured [Annexed]:
- 5. Fee paid on.......Rs.....receipt/challan/transaction id.
- 6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:	
Date:	

(Name and designation)
[To be signed digitally]

ANNEXURE

Sl. No.	Generic name	Class of medical device	Quantity proposed to be manufactured

FORM MD-13

[Refer sub-rule (3) of rule 31]

LICENCE TO MANUFACTURE MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGATIONS OR TEST OR EVALUATION OR DEMONSTRATION OR TRAINING

1.	M/s		. <u>Ä</u>	of	 ,	is c hereby	licensed	to
ma	anufa	cture the me	edical de	vice(s) spe	cified sb	elow for the	e purposes	of
		investigation		or evalua	7/ / Juli	demonstration	on or train	ing
,	Sl. No.	Generic name		edical device EALTH, GO		o permitted to be	manufacture	
		s licence is a	•	-	ions of t	he Medical I	Devices Ru	les,
		s licence shad below.	all be in fo	orce for a	period o	f three years	from the d	late
Pla	ace:				C	Central Licens	ing Author	ity
Da	ate:		•••••			[To be sign	ed digitally	.]

[Refer sub-rule (1) of rule 34]

APPLICATION FOR ISSUE OF IMPORT LICENCE TO IMPORT MEDICAL DEVICE

- 1. Name of authorised agent:
- 2. Nature and constitution of authorised agent: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 3. (i) Corporate/registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence or registration certificate:
- (iii) Address for correspondence: [corporate / registered office / authorised agent]
- 4. Particulars of overseas manufacturer, manufacturing site(s):

Sr.	Name and address of manufacturer Name and address of manufacturing site (full address with telephone, fax and e- (full address with telephone, fax and e-
	mail address of the manufacturer) and address of the manufacturing site)
	MEALTH COVERNME

- 5. Details of medical device(s) to be imported [Annexed]:
- 6. Whether substantial equivalence to a predicate device is claimed: (Yes/No)
- 8. I have enclosed the documents as specified in the Fourth Schedule for grant of licence to import medical device(s).
- 9. I hereby state and undertake that:

aı 201		netics	Act, 19	940 (23	of 194	40) a	and the M	edica	l Dev	ices Ru	ıles,
Pla	ce:	•••••						Signa	ature		
Dat	e:	•••••	•••••		•••		(1)	Name	and d	esignat	ion)
							[To be	signe	d digit	ally]	
				\boldsymbol{A}	NNEX	CURI	E				
SI. No.	Generic name	Model No.	Intended use	Class of medical device	Materia	al of ction CO _N	Dimension (if any)	Shelf life	Non-	Brand Name register underTr Marks 1999)	rade
			A				GP.				
			CENTR.)RM N b-rule (// II	15 Frule 36]	NON			
		LI	CENCE	TO IM	PORT	ME	DICAL D	EVI	CE		
Lic	ence No).:		manufa	सत्यमेव	जयते	MENTOF				
	1. M/s.		1.	76,	ALTH, GO	over	lame, fu		ddress		per
	of lice	author nsed t	ised age o impor	ent with t the m	telepl edical	none devi	ence $\frac{62}{2}$ [or rand e-mace(s) man ite as specified	ail ac ufact	ddress) ured b	is her	reby
2. lice	Detail nce.	s of o	overseas	manuf	acturer	and	manufac	turing	g site	under	this
Name & address of overseas Name & address of manufacturer (full address with manufacturing site (full address No. telephone and e-mail address of the manufacturer) manufacturing site)							ddress				

(i) I shall comply with applicable provisions of the Drugs

ANNEXURE

Date:

SI. No.	Generic name	Mod el No.	Intended use	Class of medical device	ARD CONTR Material of construction	Dimension (if any)	Shelf life	Sterile or Non- sterile	Brand Name (if registered under Trade Marks Act, 1999)
			CI	osco	A CD	sco			

FORM MD-16 [Refer sub-rule (2) of rule 40] APPLICATION FOR LICENCE TO IMPORT MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGATIONS OR TEST

Seal or Stamp

- 1. Name of applicant
- 2. Address of applicant including telephone number, mobile number, fax number and e-mail id

OR EVALUATION OR DEMONSTRATION OR TRAINING

- 3. Name and Address of device manufacturer
- 4. Name and Address of site(s) where test or evaluation is proposed to be conducted
- 5. Details of medical device(s) to be imported [Annexed]

- 6. Brief description of the medical device
- 7. Purpose of import
- 8. Justification for quantity to be imported
- 9. An undertaking stating that required facilities including equipment, instrument and personnel have been provided to test or evaluate medical device
- 10. An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial number 7 and shall not be used for commercial purpose

11.	Fee paid	l on		Rs		receip	t/cha	ıllan/tra	ansaction
id	-	•••••		STANI	ARD CONTR	- -			
12.	I hereb	y stat f the	e and u	ndertake	e that, I sha metics Act	1940 (2)	with	n all a 1940)	pplicable
Med Plac	provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017. Place: Signature Date: (Name and designation) To be signed digitally)								
SI.			Intended Use	Class of medical device	H, GOVERNM Material of construction	Dimension	Shelf life	Sterile or Non- sferile	Quantity to be imported

[Refer sub-rule (1) of rule 41]

LICENCE TO IMPORT MEDICAL DEVICES FOR THE PURPOSES OF CLINICAL INVESTIGATIONS OR TEST OR EVALUATION OR DEMONSTRATION OR TRAINING

1. M/s	• • • • • • • • • • • • • • • • • • • •	is hereby licensed to import the medical
device	specified be	low from M/s
(Name	and full addre	ess of overseas manufacturer) for the purposes of clinical
		test or evaluation or demonstration or training
		s or test or evaluation or is to be carried out).
		,
SI.	Generic	Class of medical Quantity permitted to be
No.	пате	device imported
2. T	his licanca is	subject to conditions prescribed under the Medical
		2
Device	s Rules, 2017.	
3. Th	uis licence sha	all, unless previously suspended or revoked, be in force
		years from the date specified below:—
Place.		
Tacc	•	Contai Licensing Authority
Date:		[To be signed digitally]
Dute		[10 se signed digitality]
		CDSCO AM CDSCO
		FORM MD-18
		Refer sub-rule (1) of rule 42
A DDI	I ICATION E	OR LICENCE TO IMPORT INVESTIGATIONAL
		CES FOR THE PURPOSES BY A GOVERNMENT
HOS	PITAL OR S.	TATUTORY MEDICAL INSTITUTION FOR THE
		TREATMENT OF PATIENTS
		(Name and designation)
of	• • • • • • • • • • • • • • • • • • • •	(Name of the Government Hospital or Statutory
Medica	al Institution)	hereby apply for a licence to import small quantities of
investig	gational med	dical device specified below manufactured by
M/s		(Name and full address of overseas manufacturer) for
		of treatment of patients for the
		(Name of the disease)
		(name and address of the hospital).
ш	•••••	(name and address of the nospital).
2. De	tails of medica	al device to be imported:

Name of the investigational Name and address of the Quantities which may be Medical device imported					
 I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017. A fee of Rshas been credited to the Government under the 					
Head through Challan/receipt Nodated(copy attached).					
Place: Signature.					
Date: Name. Seal or Stamp. Certificate C					
Seal or Stamp					
FORM MD-19 [Refer sub-rule (2) of rule 42] LICENCE TO IMPORT INVESTIGATIONAL MEDICAL DEVICE BY A GOVERNMENT HOSPITAL OR STATUTORY MEDICAL INSTITUTION FOR THE TREATMENT OF PATIENTS Licence No					

1. Dr	(Name and designation) of(Name
of Hospital or Statutory	Medical Institution) hereby grant licence to import
from M/s	(Name and full address of manufacturer) the medical
	for the purpose of treatment of patients for the
-	ne of the disease) at(name and
address of the hospital).	ie of the disease) at(name and
address of the hospital).	
2. Details of medical de	evice to be imported:
Name of medical device	Quantities which may be imported
	<u> </u>
3. This licence shall, unl	ess previously suspended or revoked, be in force for a the date of issue specified above. Central Licensing Authority Seal or Stamp FORM MID-20 Refer sub-rule (2) of rule 43]
a period of one year from	the date of issue specified above.
	TANDARD CONTA
Place:	Central Licensing Authority
	S STATE OF THE STA
Date:	Seal or Stamp
I'A	
E	FORM MD-20
APPLICATION	FOR PERMISSION TO IMPORT SMALL
QUANTITY OF N	EDICAL DEVICES FOR PERSONAL USE
To:	्रि _{र्य} सत्यमेव जयते 🚜 ^{०९}
	OF HEALTH, GOVERNMENT
The Central Licensing A	uthority,
Sir/Madam,	
1. Iresident of.	by occupation hereby apply for a
permission to imp	ort the medical device specified below for personal
•	d by(Name and full address of
	he treatment of(name of the disease)
manaractarery for t	ne treatment of(name of the disease)
Name of medical device	Quantity ivhich may be imported
Traine of medical device	Quantity tritten may be imported
2. The prescription from	om a registered medical practitioner prescribing the
1 1	

need for the said medical device is attached.

3. The particular of the patients is specified below:—

Name	Age	Gender	Complete 1	Address		
Place:	•••••					
Date:				Signature	of	applicant

FORM MD-21

[Refer sub-rule (3) of rule 43]

PERMISSION TO IMPORT OF SMALL QUANTITY OF MEDICAL DEVICES FOR PERSONAL USE

Permit No	A.	Date	NZ.	
	CEN	ereby permitted to	101	nedical device
manufactured	by	cified below for pe	(Na	
	PL	सत्यमेव जयते	art of	
Name of the m	edical device	HEALTH, GOVERNM	Quantity	

- 2. This licence is subject to conditions prescribed in the Medical Devices Rules, 2017.
- 3. This licence shall, unless previously suspended or revoked, be in force for a period of one hundred and eighty days from the date of issue specified above.

Central Licensing Authority

Seal or Stamp

FORM MD-22

[Refer sub-rule (1) of rule 51]

APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL INVESTIGATION OF AN INVESTIGATIONAL MEDICAL DEVICE

1. Name of applicant:	
2. Nature and constitution of applicant:	
(i.e. proprietorship, partnership including private or public company, society, trust, ot	•
3. (i) Sponsor address including telephonumber and e-mail id:	one number, mobile number, fax
(ii) Clinical investigation site address inc number, fax number and e-mail id:	-
(iii) Address for correspondence:	WTROL ORO
4. Details of investigational medical devi-	ce(s) and clinical investigation site
	challan/transaction id
7. I have enclosed the documents as spe Medical Devices Rules, 2017.	cified in the Seventh Schedule of
8. I hereby state and undertake that:	
(i) I shall comply with all the provisions 1940 and the Medical Devices Rules, 2017.	<u> </u>
Place:	Signature
Date:	(Name and designation)

ANNEXURE

[To be signed digitally]

SI. No.	Generic name	Intended use	Class of medical device
SI. No.	Name and address ofsite(s)	Ethics Committee details	Name of Principal Investigator

FORM MD-23
[Refer clause (i) of rule 52]
PERMISSION TO CONDUCT CLINICAL INVESTIGATION
Permission No
1. M/s(Name and full address)
1. M/s(Name and full address) is hereby granted permission to conduct clinical investigation for following
investigational medical device as per clinical investigation
plandated in the below mentioned clinical
investigation sites.
2. Details of investigational medical device(s) and clinical investigation site
[Annexed].
3. This permission is subject to conditions as prescribed under Medical
3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.
Place: Central Licensing Authority
Date: [To be signed digitally]
ANNEXURE
Details of investigational medical device(s):
SI. No. Generic name Intended use Class of medical device
Details of Clinical investigation site:
SI. Name and address Ethics Committee Name of Principal
No. of site(s) details Investigator

[Refer sub-rule (2) of rule 59]

APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL PERFORMANCE EVALUATION OF NEW *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

- 1. Name of applicant:
- 2. Nature and constitution of applicant: CON
- (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 3. (i) Sponsor address including telephone number, mobile number, fax number and e-mail id: CDSCO CDSCO
- (ii) Laboratory(ies) or institution(s) address including telephone number, mobile number, fax number and e-mail idea a
- (iii) Address for correspondence:
- 4. Details of new *in vitro* diagnostic medical device and laboratory(ies) or institution(s) [Annexed].
- 5. Clinical performance evaluation plan number with date:
- 7. I have enclosed the documents as specified in sub-rule (3) of rule 59 of Medical Devices Rules, 2017.
- 8. I hereby state and undertake that:
- (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

Place:			Signature		
Date:		•••••	(Name and designation)		
			[To be signed digitally]		
		AN	<i>NEXURE</i>		
Details	of new in vitro	diagnostic m	edical device		
SI. No.	Generic name	Intended use	Class of medical device		
Details	of laboratory(i	es)/ institution	n(s) involved		
	Tame and address Institution(s)	of laboratory (i	es) Ethics Committee Name of Principal details Investigator		
		7	Z Z		
	L	FOR	M MD-25		
D	FDMISSION '	All El Sam	ule (5) of rule 59] CLANICAL PERFORMANCE		
	ALUATION	***	VITRO DIAGNOSTIC MEDICAL		
Z,		OF HE D	EVICE H, GOVERNMEN		
Permiss	sion No				
manufa conduct device	cturer with tel t clinical perfor as	lephone and rmance evaluate per cli	(Name and full address of e-mail) is hereby granted permission to ation of following new <i>in vitro</i> diagnostic nical performance evaluation		
_	ory(ies) or insti		on the below mentioned lved.		
	tails of new in on(s) [Annexed	_	tic medical device and laboratory (ies) or		

3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.

Place:	Central Licensing Authority
Date:	[To be signed digitally]

ANNEXURE

Details of new in vitro diagnostic medical device

SI. No.	Generic name	Intended use	Class of medical device

Details of laboratory(ies)/institution(s) involved

SI.	Name and address of la	boratory Ethics Committee	Name of	Principal
No.	(ies)/institution^)	details	Investigator	
	O	GENERAL Z		

FORM MD-26
[Refersab-rule (1) of rate 63]

APPLICATION FOR GRANT OF PERMISSION TO IMPORT /MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF MEDICAL DEVICE WHICH DOES NOT HAVE PREDICATE MEDICAL DEVICE

- Name of applicant: 1.
- Nature and constitution of applicant:
- (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 3. (i) Corporate / registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Manufacturing site / Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence $\frac{63}{2}$ [or registration certificate]:
- Address for correspondence: (iii)

[Corporate/registered office/manufacturing site/ authorised agent]

4. Particulars of Manufacturer, Manufacturing site(s):

No	address with telephone, fax and e-mail	Name and address of manufacturing site (full address with telephone, fax and email address of the manufacturing site)

5.	Details of medical	l device(s) to be imported	or manufactured	[Annexed].
- •			, es s e map sact es	01 111001101101000000000000	

- 6. Fee paid on......Rs....receipt/challan/transaction id.....
- 7. I have enclosed the documents as specified in the Part IV of the Fourth Schedule to the Medical Devices Rules, 2017.

P	lac	ce:			GS STANDA	ARD CONTROL	Signat	ure	
	at		••••	707			(Name and d		1)
				CENTR	[To be sig	med digitally	AT	C	,
					cosco	CDS EXURE	The same of the sa		
S	II.	Generic	Model	Intended 1	Class of medical	Haterial of	Dimension	Shelf	rile o

FORM MD-27

(if any)

life

sterile

[Refer sub-rule (2) of rule 63]

PERMISSION TO IMPORT OR MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF MEDICAL DEVICE WHICH DOES NOT HAVE PREDICATE MEDICAL DEVICE

Perm	ission No		•••••						
manu	ıfacturer	with	telephone, (address	and	e-mail)	havir	ng n	nanufa	cturing

No.

name

No.

use

permitted to import/ manufacture for sale or for distribution of following medical devices.

- 2. Details of medical device(s) to be imported or manufactured [Annexed].
- 3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act (23 of 1940) and the Medical Devices Rules, 2017.

Place:	Central Licensing Authority
Date:	[To be signed digitally]

ANNEXURE

							Sterile/	
SI.	Generic	Brand	Model		Intended			
				Dimension	NDARD C	Shel f life	Non-	Class of medical device
No.	Name	name	No.	, GS S !!	Use	YOU		
				SED SE	14/33)	Pa	Sterile	
			4	7	38		7	
			Q;	ř j	3311135253	0.73	<u> </u>	

CDSCO MD-28 [Refer sub-rule (1) of rule 64]

APPLICATION FOR GRANT OF PERMISSION TO IMPORT OR MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF NEW IN VITRO DIAGNOSTIC MEDICAL DEVICE

- 1. Name of applicant:
- 2. Nature and constitution of applicant:
- (i.e. proprietorship, partnership including Limited Liability Partnership, private/public company, society, trust, other to be specified)
- 3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
- (ii) Manufacturing site / authorised agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence ⁶⁴[or registration certificate]:

(iii) Address for correspondence:

[Corporate / registered office / manufacturing site/ authorised agent]

4. Particulars of Manufacturer, Manufacturing site(s):

No	address with telephone, fax and e-mail	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

- 5. Details of new *in vitro* diagnostic medical device to be imported or manufactured [Annexed].
- 6. Fee paid on......Rs....receipt/challan/ transaction id.....
- 7. I have enclosed the documents as specified in the Part IV of the Fourth Schedule Medical Devices Rules, 2017.

	NI SEE
Place:	VC DW
1 1acc	44 17
ш	11 11
	V X

Signature

Date:	CDS	CO
	3	M

(Name and designation)

[To be signed digitally]

ANNEXURE

	3.7	Intended use	medical	Material of construction	Dimension (if any)	Shelf life	Sterile or Non- sterile

FORM MD-29

[Refer sub-rule (2) of rule 64]

PERMISSION TO IMPORT OR MANUFACTURE NEW IN VITRO DIAGNOSTIC MEDICAL DEVICE

1. The new *in vitro* diagnostic medical device(s) specified below manufactured by M/s...... (Name and full address of manufacturer with telephone, and e-mail) having manufacturing site

(address of manufacturing site), is hereby permitted to import or manufacture.						
2. Details of new <i>in vitro</i> diagnostic medical device to be imported or manufactured [Annexed].						
3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.						
Place: Central Licensing Authority						
Date:						
ANNEXURE						
SI. Generic Brand Model No. Dimension Intended Shelf-life Noti-Sterile Sterile Sterile						
FORM MD-30 [Refer Sub-rule (1) of Fille 67] MEMORANDUM TO THE CENTRAL MEDICAL DEVICE TESTING LABORATORY HEALTH, GOVERNMENT The Director,						
Central Medical Device Testing Laboratory,						
From						
1. I send herewith, under the provisions of sub-section (4) of section 25 of the Drugs and Cosmetics Act, 1940 (23 of 1940), sample(s) of a medical device purporting to be						
2. The distinguishing number on the packet is						
Particulars of offence alleged						

4.	Matter on which opinion is required
5.	A fee of Rshas been deposited in Court.
Dat	te
	Magistrate
	FORM MD-31
	[Refer sub-rule (4) of rule 67]
	CERTIFICATE OF TEST OR EVALUATION BY THE CENTRAL
	MEDICAL DEVICE TESTING LABORATORY
1.C	Certified that the samples, bearing numberpurporting
	be a sample ofreceived onwith
	morandum No dated from has
bee	en tested / evaluated and that the result of such test/evaluation is as stated
bel	OW. STANDARD CONTRO
*3. star 194	The condition of the seals on the packet on receipt was as low
	tails of results of testing or evaluation with protocols of test or evaluation blied
Dat	te Director of Central Medical Device Testing
	Laboratory / other Authorised Officer
	f opinion is required on any other matter, the paragraph should be suitably ended.

[Refer sub-rule (2) of rule 68]

REPORT OF TEST OR EVALUATION OF MEDICAL DEVICES BY MEDICAL DEVICE TESTING OFFICER

1. It is certified that the samples having serial number of memorandum or receipt number
2. The conditions of seals on the packet or on portion of sample or container were as follows
3. Based upon the test or evaluation and in the opinion of undersigned the sample is of standard quality/not of standard quality/adulterated/misbranded/spurious, as defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) for the reasons given below:—
Date Medical Device Testing Officer
APPLICATION FROM A PURCHASER FOR TEST OR EVALUATION OF A MEDICAL DEVICE UNDER SECTION 26 OF THE DRUGS AND COSMETICS ACT, 1946 (23 OF 1940) To: The Central Licensing Authority, ALTH, GOVERNMENT OF THE DRUGS AND COSMETICS ACT, 1946 (23 OF 1940)
 Full name and address of the applicant Occupation
3. Name of medical device purporting to be contained in the
sample
device was purchased.
5. Date on which purchased(invoice
attached)
6. Reasons why the medical device is being submitted for test or evaluation

7. A fee	of rupees		• • • • • • • • • • • • • • • • • • • •	•••••	as c	charged by	medical
device	testing	laboratory	has	been	paid	under	receipt
number	date	ed:					
	•	e that the me			•		
evaluation	n was purc	hased by or fo	r me. I i	further de	clare tha	it the samp	ole of the
		g sent for test			•	-	ırchased
and has no	ot been tan	npered with in	any wa	y to redu	ce its po	tency.	
Data	•••••					Signatu	ro
Datc	•••••	•••••			S	eal or Star	
		FC	RM M	D_34	5	cai oi stai	пр
		_	efer rul	_			
ORDER	IINDER (CLAUSE (c) (•		ON (1) (OF SECT	ION OF
		SS AND COS					
REOI	IIRING A	DEDCONIN	WARD.	PISPOS	E OF S	TOCK IN	,, HIS
TLE Q		PERSOINT PC	SSESS	ION			
		OF G			AGA.		
Wher	eas. I have	e reason to be	lieve th	at the sto	ocks of	medical de	evices in
		tailed below c	SOUND TO SO	NOME C			
-		netics Act 194	V 1 1 1 1 1	- 11			
_			dololo dolo	STATE OF THE PARTY			
Now,	therefore,	I hereby requi	re you ı	ınder claı	use (c) o	f sub-secti	on (1) of
Section 2	2 of the	said Act, not	to disp	ose of th	ré said	stock for	a period
of	days 1	from the date (of this o	rdenmen			
Date:					Med	ical Device	e Officer
						Seal o	or Stamp
	Details of stock of medical devices						
Date:	•••••				Med	ical Device	e Officer
						Seal o	or Stamp

[Refer rule 74]

RECEIPT FOR STOCK OF MEDICAL DEVICES FOR RECORD, REGISTER, DOCUMENT OR MATERIAL OBJECT SEIZED UNDER CLAUSE (c) OR CLAUSE (cc) OF SUB-SECTION (1) OF SECTION 22 OF THE DRUGS AND COSMETICS ACT (23 OF 1940)

The stock of medical devices or records,	registers, documents or mate	rial
objects, detailed below has/have this day	been seized by me under	the
provisions of clause (c) or clause (cc) of sub	e-section (1) of section 22 of	the
Drugs and Cosmetics Act, 1940 (23 c	of 1940), from the premi	ises
ofsituated at		
Date:	Medical Device Office	r
	Seal or Sta	mp
Details of stock of medical devices or reco	ords, registers, documents o	r
material objects s	seized	
Date:	Medical Device Office	er
	Seal or Sta	mp
FORM MD-3	6	
5 Refer rule 76		
INTIMATION OF PERSON FROM W	HOM SAMPLE IS TAKEN	ſ
To:		
E _N	A	
I have this day taken from the prem	ffeet	
samples of medical devices spe	cified below for the purpose	of
test or evaluation.	PIQ	
Date: सत्यमेव जयते	Madical Davice Office	\r
Date	Sand or Sto	il mn
Details of sample of mos	Medical Device Office Seal or Sta lical devices	.mp
Date:	Medical Device Office	
Date		
	Seal or Sta	.mp
FORM MD-3	27	
[Refer rule 77		
		DE
RECEIPT FOR SAMPLE OF MEDICAL FAIR PRICE TENDERED THEREOF U	• •	
SECTION 23 OF THE DRUGS AND C		JI
REFUSED	OSMETICS AC1, 1940 IS	
To:		
Whereas I, thisday of,	have taken from the premi	ses
situated atsamples of medical devices as	-	- ~

And whereas I had offered to you rupees.....as the fair price of the samples of aforesaid medical devices taken; And whereas, you have refused to accept the fair price tendered thereof; Now, therefore, I give you this receipt as the fair price tendered for the samples of the medical devices taken by me. Date: Medical Device Officer Seal or Stamp FORM MD-38 [Refer sub-rule (1) of rule 78] MEMORANDUM TO MEDICAL DEVICE TESTING OFFICER Serial No. of Memorandumas STANDARD CONT From: To: The Medical Device Testing Officer The sample of medical device described below is enclosed for test or evaluation under the provisions of clause (i) of sub-section (4) of section 23 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

Details of samples:

The sample of medical device has been marked by me with following mark.

Details of sample of medical device with name of medical device which is purports to contain—

Date:..... Medical Device Officer Seal or Stamp

FORM MD-39

[Refer sub-rule (1) of rule 81]

APPLICATION FOR GRANT OF REGISTRATION TO MEDICAL DEVICE TESTING LABORATORY FOR CARRY OUT TEST OR EVALUATION OF A MEDICAL DEVICE ON BEHALF OF MANUFACTURER

1. Name of applicant:			
2. Nature and constitution of applicant:			
(i.e. proprietorship, partnership including private or public company, society, trust, other	-		
3. (i) Corporate/registered office address mobile number, fax number and e-mail id:	including telephone number,		
(ii) Testing laboratory address including telefax number and e-mail id:	ephone number, mobile number,		
(iii) Address for correspondence:			
[Corporate office / testing laboratory] CONT	iRo,		
[Corporate office / testing laboratory] CONT 4. Details of medical device(s) to be tested of			
5. Fee paid on	receipt/challan/transaction		
6. I have enclosed the documents as specific	ed in the sub-rule (2) of rule 82		
of Medical Devices Rules, 2017. सत्यमेव जयते 7. I hereby state and undertake that; Govern	MEIL		
(i) the testing laboratory is ready for insinspection onin accordance we Devices Rules, 2017.	spection of shall be ready for		
(ii) I shall comply with the applicable Cosmetics Act, 1940 (23 of 1940), and the Me	•		
Place:	Signature		
Date:	(Name and designation) [To be signed digitally]		
ANNEXURE			
Sl.No. Generic name Class of medical devices			

[Refer sub-rule (3) of rule 83]

CERTIFICATE OF REGISTRATION TO MEDICAL DEVICE TESTING LABORATORY FOR CARRY OUT TEST OR EVALUATION OF A MEDICAL DEVICE ON BEHALF OF MANUFACTURER

Registration No.:
1. M/s(Name of the firm) situated
at (full address with telephone and e-mail) has been
registered as a Medical Device Testing Laboratory for carry out Test or
Evaluation of a medical device on behalf of manufacturer under the Medical
Evaluation of a medical device on behalf of manufacturer under the Medical Devices Rules, 2017.
2. Details of medical device(s) to be tested or evaluated [Annexed].
3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.
Place: Central Licensing Authority
Place: entral Licensing Authority Under Harden जयते Date: Harden जयते Date: Harden Governme To be signed digitally]
ANNEXURE
Sl.No. Generic name Class of medical devices

65[Form MD-41

[See sub-rule (2) of rule 87A]

APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR

DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

- 1. Name of applicant:
- 2. Address of the premises to be registered:
- 3. Contact details of applicant including telephone number, mobile number, fax number and email id:
- 4. Nature and constitution of applicant: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
- 5. Name, qualification and experience of competent person appointed:

6. Fee paid	on STANDARD CONTROL Rs_
receipt/challan/tra	nsaction Id
7. I have enclosed	the documents as specified in the sub-rule (3) of rule 87A
of the Medical De	vices Rules, 2017.
Place:	CDSCO CDSCO
Date:	सत्यमेव जयते सत्यमेव जयते हैं। अपनि सत्यमेव सत्यमेव हैं। अपनि सत्यमेव हैं। अप
	HEALTH GOVE Name, designation & signature of
	Director/Proprietor/Partner

Form MD-42

[See sub-rule(4) of rule 87A and sub-rule (1) of rule 87C]

REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR FFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

Registration No.:			
1.M/s,	(Name	of the	firm)
situated at	(ful	laddress	with
telephone and e-mail) has been registered to sell,	stock, exhi	bit or off	er for
sale or distribute a medical device including in	<i>vitro</i> diag	nostic m	edical
device under the Medical Devices Rules, 2017.			

2. Name and qualification of competent person:	
3. This registration is subject to the conditions as specified in the Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules	•
Place:	
Date: State Licensin	ng Authority
Form MD-43 [See sub-rule (8) of rule 87B] Form in which the Inspection Book shall be maintain	ned
(A) The cover of the inspection book shall contain the following particulars: 1. The name and address of the registration certificate holder 2. Registration certificate number CDSCO (B) (i) The pages of the inspection book shall be serially numbere stamped by the State Licensing Authority* The pages, other than the last pages, shall have the following particulars: Name and designation of the Medical Device Officer who in premises: Date of inspection	d and duly the first and
Observations of the Medical Device Officer	
Signature of the Medical De	evice Officer
(ii) The first and last pages of the inspection book shall be endo State Licensing Authority with the following words, namely:—	orsed by the
Inspection book maintained by M/s for Registration number	
Form MD-43 under the Medical Devices Rules,	
singer are reconstructs,	•