



GOVERNMENT OF INDIA

**MINISTRY OF HEALTH AND FAMILY
WELFARE**

(Department of Health)

**THE DRUGS AND COSMETICS ACT
AND RULES**

THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

(As amended up to the 31st December, 2016)

and

THE DRUGS AND COSMETICS RULES, 1945

(As amended up to the 31st December, 2016)

¹[SCHEDULE - H

(See Rules 65 and 97)

PRESCRIPTION DRUGS

1.	Abacavir	38.	Artesunate
2.	Abciximab	39.	Articaine hydrochloride
3.	Acamprosate calcium	40.	Atenolol
4.	Acebutol hydrochloride	41.	Atracurium besylate injection
5.	Aclarubicin	42.	Atorvastatin
6.	Albendazole	43.	Auranofin
7.	Alclometasone dipropionate	44.	Azathioprine
8.	Actilyse	45.	Aztreonam
9.	Acyclovir	46.	Bacampicillin
10.	Adenosine	47.	Baclofen
11.	Adrenocorticotrophic hormone (acth)	48.	Balsalazide
12.	Alendronate sodium	49.	Bambuterol
13.	Alopurinol	50.	Barbituric acid
14.	Alphachymotrypsin	51.	Basiliximab
15.	² [Alprazolam	52.	Benazepril hydrochloride
16.	Alprostadil	53.	Benidipine hydrochloride
17.	Amantadine hydrochloride	54.	Benserazide hydrochloride
18.	Amifostine	55.	Betahistine dihydrochloride
19.	Amikacin sulphate	56.	Bethanidine sulphate
20.	Amiloride hydrochloride	57.	Bezafibrate
21.	Amineptine	58.	Bicalutamide
22.	Aminoglutethimide	59.	Biclotymol monohydrate /lactate
23.	Amino salicylic acid	60.	Bifonazole
24.	Amiodarone hydrochloride	61.	Bimatoprost
25.	Amitriptyline	62.	Biperiden hydrochloride
26.	Amlodipine besylate	63.	Biphenyl acetic acid
27.	Amoscanate	64.	Bitoscanate
28.	Amoxopine	65.	Bleomycin
29.	Amrinonelactate	66.	Primonidine tartrate
30.	Analgin	67.	Bromhexine hydrochloride
31.	Androgenic anabolic, oestrogenic & progestational substances	68.	Bromocriptine mesylate
32.	Antibiotics	69.	Budesonide
33.	Apraclonidine	70.	Bulaquine
34.	Aprotinin	71.	Bupivacaine hydrochloride
35.	Organic compound of arsenic	72.	Bupropion
36.	Arteether	73.	Buspirone
37.	Artemether	74.	Butenafine hydrochloride
		75.	Butorphanol tartrate

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1. Subs. by G.S.R. No.160(E), dated 16.3.2006 .
 2. Omitted by G.S.R 588(E) dated 30-8-2013
 3. Omitted by G.S.R 602(E) dated 19-7-2010
 4. Omitted by G.S.R 724(E) dated 7-11-2013

76.	Cabergoline	122.	Clobetasone 17-butyrate
77.	Calcium dobesilate	123.	² [Clofazimine]
78.	Candesartan	124.	Clofibrate
79.	Capecitabine	125.	Clonazepam
80.	Captopril	126.	Clonidine hydrochloride
81.	Carbidopa	127.	Clopramide
82.	Carbocisteine	128.	Clopidogrel bisulphate
83.	Carboplatin	129.	Clostebolacetate
84.	Carboquone	130.	Clotrimazole
85.	Carisoprodol	131.	Clozapine
86.	L-carnitine	132.	² [Codeine]
87.	Carteolol hydrochloride	133.	Colchicine
88.	Carvedilol	134.	Corticosteroids
89.	Cefadroxyl	135.	Cotrimoxazole
90.	Cefatoxime sodium	136.	Cyclandelate
91.	Cefazolin sodium	137.	Cyclosporins
92.	² [Cefdinir]	138.	Daclizumab
93.	Cefepime hydrochloride	139.	Danazole
94.	Cefetamet pivoxil	140.	Dapsone
95.	Cefpirome	141.	Desloratadine
96.	Cefpodoximepoxetil	142.	Desogestrol
97.	Ceftazidime pentahydrate	143.	Dexrazoxane
98.	Ceftizoxime sodium]	144.	Dextranomer
99.	Cefuroxime	145.	² [* * *]
100.	Celecoxib	146.	Dextropropoxyphene
101.	Centchroman	147.	² [Diazepam]
102.	Centbutindole	148.	Diazoxide
103.	Centropazine	149.	Diclofenac sodium/potassium/acid
104.	Cetirizine hydrochloride	150.	Dicyclomin hydrochloride
105.	² [Chlordiazepoxide	151.	Didanosine
106.	Chlormezanone	152.	Digoxine
107.	³ [* * *]	153.	Dilazep hydrochloride
108.	Chlorpromazine	154.	Diltiazem
109.	Chlorzoxazone	155.	Dinoprostone
110.	Ciclopiroxolamine	156.	² [Diphenoxylate, its salts]
111.	Cimetidine	157.	Dipivefrin hydrochloride
112.	Cinnarizine	158.	Di-sodiumpamidronate
113.	Ciprofloxacin hydrochloride	159.	Disopyramide
114.	Cisplatin	160.	Docetaxel
115.	Citalopram hydrobromide	161.	Domperidone
116.	Clarithromycin	162.	Donepezil hydrochloride
117.	Clavulanic acid	163.	Dopamine hydrochloride
118.	Clidiniumbromide	164.	Dothiepin hydrochloride
119.	Clindamycin	165.	Doxapram hydrochloride
120.	Clobazam	166.	Doxazosin mesylate
121.	Clobetasol propenate	167.	Doxepin hydrochloride

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Drugs and Cosmetics Rules 1945

168.	Doxorubicin hydrochloride	213.	Fosfestril sodium
169.	Drotrecogin-alpha	214.	Fosinopril sodium
170.	Ebastine	215.	Fosphenytoin sodium
171.	Econazole	216.	Fotemustine
172.	Efavirenz	217.	Gabapentin
173.	Enalapril meleate	218.	Galanthamine hydrobromide
174.	Enfenamic acid	219.	Galamine, its salts, its quaternary compound
175.	Epinephrine	220.	Gancyclovir
176.	Epirubicine	221.	Ganirelix
177.	Eptifibatide	222.	Gatifloxacin
178.	Ergot, alkaloids of whether hydrogenated or not, their homologues, salts	223.	Gemcitabine
179.	Esomeprazole	224.	Gemfibrozil
180.	Estradiol succinate	225.	Gemtuzumab
181.	Estramustine phosphate	226.	Genodeoxycholic acid
182.	Etanercept	227.	Gliclazide
183.	Ethacridine lactate	228.	Glimepiride
184.	² [Ethambutol hydrochloride]	229.	Glucagon
185.	Ethamsylate	230.	Glycopyrrolate
186.	Ethinylloestradiol	231.	Glydiazinamide
187.	² [Ethionamide]	232.	Goserelin acetate
188.	Etidronate disodium	233.	Granisetron
189.	Etodolac	234.	Guanethidine
190.	Etomidate	235.	Gugulipid
191.	Etoposide	236.	Halogenated hydroxyquinolines
192.	Exemestane	237.	Haloperidol
193.	Famciclovir	238.	Heparin
194.	Famotidine	239.	Hepatitis b. Vaccine
195.	Fenbendazole	240.	Hyaluronidase
196.	Fenofibrate	241.	Hydrocorisone 17-butyrate
197.	Fexofenadine	242.	Hydrotalcite
198.	Finasteride	243.	Hydroxizine
199.	Flavoxate hydrochloride	244.	Ibuprofen
200.	5-fluorouracil	245.	Idebenone
201.	Fludarabine	246.	Indapamide
202.	Flufenamic acids	247.	Imipramine
203.	Flunarizine hydrochloride	248.	Indinavir sulphate
204.	Fluoxetine hydrochloride	249.	Indomethacin
205.	Flupenthixol	250.	Insulin human
206.	Fluphenazine enanthate and decanoate	251.	Interferon
207.	Flurazepam	252.	Intravenous fat emulsion
208.	Flurbiprofen	253.	Iobitridol
209.	Flutamide	254.	Iohexol
210.	Fluticasone propionate	255.	Iopamidol
211.	Fluvoxamine maleate	256.	Iomeprol
212.	Formestane	257.	Iopromide
		258.	Irbesartan
		259.	Irinotecan hydrochloride

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Drugs and Cosmetics Rules 1945

260.	Iron preparation for parenteral use	304.	Megestrol acetate
261.	Isepamicine	305.	Meglumine iocarmate
262.	Isocarboxide	306.	Melagenina
263.	Isoflurane	307.	Elitracenhydrochloride
264.	Isonicotnic acid hydrazine and other-hydragine derivatives of isonicotinic acid	308.	Meloxicam
265.	Isosorbide dinitrate/ mononitrate	309.	Mephenesin, its esters
266.	Isotretinoin	310.	Mephentermine
267.	Isoxsuprine	311.	² [Meropenam]
268.	Itopride	312.	Mesterolone
269.	⁴ [***]	313.	Metaxalone
270.	Ketoconazole	314.	Methicillin sodium
271.	Ketoprofen	315.	Methocarbamol
272.	Ketorolactromethamine	316.	Methotraxate
273.	Labetalol hydrochloride	317.	Metoclopramide
274.	Lacidipine	318.	Metoprolol tartrate
275.	Lamivudine	319.	Metrizamide
276.	Lamotrigine	320.	Metronidazole
277.	Latanoprost	321.	Mexiletine hydrochloride
278.	Lefunomide	322.	Mianserin hydrochloride
279.	Lercanidipine hydrochloride	323.	Miconazole
280.	Letrozole	324.	² [Midazolam]
281.	Leuprolide acetate	325.	Mifepristone
282.	Levamesole	326.	Milrinone lactate
283.	Levarterenol	327.	Miltefosine
284.	Levobunolol	328.	Minocycline
285.	Levocetirizine	329.	Minoxidil
286.	Levodopa	330.	Mirtazapine
287.	² [Levofloxacin]	331.	Misoprostol
288.	Levovist	332.	Mitoxantrone hydrochloride
289.	Lidoflazine	333.	Mizolastine
290.	Linezolid	334.	Moclobemide
291.	Lithium carbonate	335.	Mometasone furoate
292.	Lofepamine decanoate	336.	Montelukast sodium
293.	Loperamide	337.	Morphazinamide hydrochloride
294.	Lorazepam	338.	Mosapride
295.	Losartan potassium	339.	² [Moxifloxacin]
296.	Loteprednol	340.	Mycophenolate mofetil
297.	Lovastatin	341.	Nadifloxacin
298.	Loxapine	342.	Nadolol
299.	Mebendazole	343.	Nafarelin acetate
300.	Mebeverine hydrochloride	344.	Nalidixic acid
301.	Medroxyprogesterone acetate	345.	Naproxen
302.	Mefenamic acid	346.	Narcotics drugs listed in Narcotic Drugs & Psychotropic Substances Act, 1985
303.	Mefloquine hydrochloride		

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347.	Natamycin	388.	Parp-amino salicylic acid, its salts, its derivatives
348.	Nateglinide	389.	Parecoxib
349.	N-butyl-2-cyanoacrylate	390.	Paroxetine hydrochloride
350.	Nebivolol	391.	D-penicillamine
351.	Nebumetone	392.	² [Pentazocine]
352.	Nelfinavir mesilate	393.	Pentoxifylline
353.	Netilmicin sulphate	394.	Pepleomycin
354.	Nevirapine	395.	Phenelzineh sulphate
355.	Nicergoline	396.	Phenobarbital
356.	Nicorandil	397.	Phenothiazine, derivatives of and salts of its derivatives
357.	Nifedipine	398.	Phenylbutazine
358.	Nimesulide	399.	Pimozide
359.	Nimustine hydrochloride	400.	Pindolol
360.	² [Nitrazepam]	401.	Pioglitazone hydrochloride
361.	Nitroglycerin	402.	Piracetam
362.	Norethisterone enanthate	403.	Piroxicam
363.	Norfloracin	404.	Pituitary gland, active principles of, not otherwise specified in this schedule and their salts
364.	Octylonium bromide	405.	Polidocanol
365.	Ofloxacin	406.	Polyestradiol phosphate
366.	Olanzapine	407.	Poractant alfa
367.	Omeprazole	408.	Praziquantel
368.	Ornidazole	409.	Prednimustine iothalamates
369.	Orphenadrine	410.	Prednisolone stearoylglycolate
370.	Orthoclone sterile	411.	Prenoxdiazinhydro-chloride
371.	Oxazepam	412.	Promazine hydrochloride
372.	Oxazolidine	413.	Promegestone
373.	Oxcarbazepine	414.	Propafenon hydrochloride
374.	Oxethazaine hydrochloride	415.	Propanolol hydrochloride
375.	Oxiconazole	416.	Propofol
376.	Oxolinic acid	417.	Protristylne hydrochloride
377.	Oxprenolol hydrochloride	418.	² [Pyrazinamide]
378.	Oxybutynin chloride	419.	Pyrvinium
379.	Oxyfedrine	420.	Quetiapine fumerate
380.	Oxymetazoline	421.	Quinapril
381.	Oxyphenbutazone	422.	Quinidine sulphate
382.	Oxytocin	423.	Rabeprazole
383.	Ozothine	424.	Racecadotril
384.	Paclitaxel	425.	Raloxifene hydrochloride
385.	Pancuronium bromide		
386.	Pantoprazole		
387.	Para-amino benzene sulphonamide, its salts & derivatives		

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Drugs and Cosmetics Rules 1945

426.	Ramipril hydrochloride	467.	Spectinomycin hydrochloride
427.	Ranitidine	468.	Spironolactone
428.	Rauwolfia, alkaloids of, their salts, derivatives of the alkaloids or rauwolfia	469.	Stavudine
429.	Reboxetine	470.	Sucralfate
430.	Repaglinide	471.	Sulphadoxine
431.	Reproterol hydrochloride	472.	Sulphamethoxine
432.	Rilmenidine	473.	Sulphamethoxypyridazine
433.	Riluzone	474.	Sulphaphenazole
434.	Risperidone	475.	Sulpiride
435.	Ritonavir	476.	Sulprostone hydrochloride
436.	Ritodrine hydrochloride	477.	Sumatriptan
437.	Rituximab	478.	Tacrine hydrochloride
438.	Rivastigmine	479.	Tamsulosin hydrochloride
439.	Rocuronium bromide	480.	Trapidil
440.	Ropinirole	481.	Tegaserod maleate
441.	Rosoxacin.	482.	Teicoplanin
442.	Rosiglitazone melete	483.	Telmisartan
443.	Salbutamol sulphate	484.	Temozolamide
444.	Salicyl-azo-sulphapyridine	485.	Terazosin
445.	Salmon calcitonin	486.	Terbutaline sulphate
446.	Saquinavir	487.	Terfenadine
447.	Satranidazole	488.	Terizidone
448.	Secnidazole	489.	Terlipressin
449.	Septopal beads & chains	490.	Testosteroneun decoanoate
450.	Serratiopeptidase	491.	Teratolol hydrochloride
451.	Sertraline hydrochloride	492.	Thalidomide
452.	Sibutramine hydrochloride	493.	² [Thiacetazone]
453.	Sildenafil citrate	494.	Thiocolchicoside
454.	Simvastatin	495.	Thiopropazate, its salts
455.	Sirolimus	496.	Thymogene
456.	Sisomicin sulphate	497.	Thymosin-alpha ¹
457.	S-neominophagen	498.	Tiaprofenic acid
458.	Sodiumpico sulphate	499.	Tibolone
459.	Sodium cromoglycate	500.	Timolol maleate
460.	Sodium hyaluronate	501.	Tinidazole
461.	Sodium valproate	502.	Tizanidine
462.	Sodium and maglumine iothalamates	503.	Tabramycin
463.	Somatostatin	504.	Tolfenamic acid
464.	Somatotropin	505.	Topiramate
465.	Sotalol	506.	Topotecan hydrochloride
466.	² [Sparfloxacin]	507.	² [Tramadolhydrochloride]
		508.	Tranexamic acid
		509.	Tranlycypromine, its salts
		510.	Trazodone

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511.	Tretinoin	524.	Verapamil hydrochloride
512.	Trifluoperazine	525.	Verteporfin
513.	Trifluoperidol hydrochloride	526.	Vincristine sulphate
514.	Triflusal	527.	Vinblastine sulphate
515.	Trimetazidine dihydrochloride	528.	Vindesine sulphate
516.	Trimipramine	529.	Vinorelbine tartrate
517.	Tripotassium dicitrate bismuthate	530.	Xipamide
518.	Tromantadine hydrochloride	531.	Zidovudine hydrochloride
519.	Urokinase	532.	Ziprasidone hydrochloride
520.	Valsartan	533.	Zoledronic acid
521.	Vasopressin	534.	² [Zolpidem]
522.	Vecuronium bromide	535.	Zopiclone
523.	Venlafaxine hydrochloride	536.	Zuclopenthixol

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Note:- 1. Preparations exempted under proviso to para 2 of Note to Schedule X shall also be covered by this Schedule.

2. The salts, esters, derivatives and preparations containing the above substances excluding those intended for topical or external use (except ophthalmic and ear / nose preparations containing antibiotics and/ or steroids) are also covered by this Schedule.

3. The inclusion of a substance in this Schedule does not imply or convey that the substance is exempted from the provisions of Rule 122A/122B."

¹[SCHEDULE H1 (See Rules 65 and 97)

Alprazolam	Doripenam
Balofloxacin	Ertapenam
Buprenorphine	Ethambutol Hydrochloride
Capreomycin	Ethionamide
Cefdinir	Feropenam
Cefditoren	Gemifloxacin
Cefepime	Imipenem
Cefetamet	Isoniazide
Cefixime	Levofloxacin
Cefoperazone	Meropenem
Cefotaxime	Midazolam
Cefpirome	Moxifloxacin
Cefpodoxime	Nitrazepam
Ceftazidime	Pentazocine
Ceftibuten	Prulifloxacin
Ceftizoxime	Pyrazinamide
Ceftriaxone	Rifabutin
Chlorodiazepoxide	Rifampicin
Clofazimine	Sodium Para-aminosalicylate
Codeine	Sparfloxacin
Cycloserine	Thiacetazone
Diazepam	Tramadol
Diphenoxylate	Zolpidem

Note:- Preparations containing the above drug substances and their salts excluding those intended for topical or external use (except ophthalmic and ear or nose preparations) containing above substances are also covered by this Schedule.

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1. Ins. by G.S.R 588(E) , dt. 30.8.2013.