

DRUGS CONTROL DEPARTMENT, GOVT. OF NCT OF DELHI
F-17, KARKARDOOMA, DELHI-110032
Phone: 011-22393703, 011-22393705 Fax: 011-22393707
Website: <http://drugscontrol.delhigovt.nic.in>
Email id: drugscontrol@nic.in

By Email

F. 13(15)/Misc/HQ/2017 / 7198

Dated: 28/3/25

To

✓ Sh. Sandeep Nangia (President)
Retail Distribution Chemist Alliance (RDCA)
H-O-42, Lajpat Nagar, New Delhi-110024
Email: rdea@rdea.in

KIND ATTENTION

Subject: Reporting of counterfeit version of Rabies Vaccine (Abhayrab), Batch No. KA24014 - Reg.

Sir,

This office is in receipt of a letter from Drugs Controller General (I), CDSCO (Enforcement Division), Govt. of India, regarding circulation of **Counterfeit version of Rabies Vaccine, Human (Abhayrab), Batch No. KA24014**, product of Human Biological Institute (A division of Indian Immunologicals Limited) in the markets of Delhi, Mumbai, Ahmedabad & Lucknow (Copy attached).

It is informed in the said letter that the counterfeit product exhibits several differences compared to original product and may pose a significant risk to public health and safety and is circulated in market without maintaining required cold chain (2-8°C). The comparison report has been enclosed along with this letter, which is self explanatory.

You are requested to sensitize your members on the subject and also bring the contents of this letter to their knowledge. You are advised to be vigilant regarding the sales and purchase of aforesaid products, which is to be done through proper invoices. Any relevant information so obtained in the subject matter may be communicated to this office immediately so as to take action as deemed fit against the offender(s).



(K.R. Chawla)

Head of Office/DDC/
Controlling & Licensing Authority


Encl: As above

F. 13(15)/Misc/HQ/2017

Dated:

Copy to:

- (i) All DDCs/ADCs/Drugs Inspectors, Govt. of NCT of Delhi for monitoring
- (ii) P.A. to Drugs Controller
- (iii) Guard file


(K.R. Chawla)
Head of Office/DDC/
Controlling & Licensing Authority



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

HBIK/QM/RAB:2025 / 001

Date: 13.01.2025

The Drug Controller General of India

Central Drugs Standard Control Organization (CDSCO)

FDA Bhavan, Kotla Road,

New Delhi – 110002, India

Subject: Reporting of finding of counterfeit product (Rabies Vaccine, Human (Abhayrab) in the Market

Dear Sir,

We Human Biologicals Institute (A division of Indian Immunologicals Limited), the manufacturer of an extensive range of human vaccines, mainly Rabies vaccine, TT, DTP, Pentavalent, Td, Hepatitis A, Hepatitis B and MR. It has come to our notice that a counterfeit version of our product Rabies Vaccine, Human (Abhayrab) is being circulated in the market. This counterfeit product is not manufactured, authorized, or distributed by our company and this could pose a significant risk to public health and safety.

We have identified that the counterfeit product has the same information as our product, "**Rabies Vaccine, Human (Abhayrab)**" batch No. **KA24014** was manufactured at our site, Survey No. 281 to 284 and 321, Biotech Park Phase – III, Karkapatla Village, Markook Mandal, Siddipet District – 502281, Telangana, India, and is being sold in Mumbai, Ahmedabad, Lucknow, and Delhi. This counterfeit product exhibits several differences in formulation, packaging, labelling, manufacturing, expiry date, MRP, etc., compared to our original product, which may pose a serious health risk to consumers as Rabies Vaccine, Human (Abhayrab) is a life-saving medicine which is meant to prevent Rabies, a 100% fatal disease. It is also observed that the product is being circulated in the market without maintaining the required cold chain (2-8°C).

संचेन : सर्वे नं. 281-284 & 321, बयोटेक पार्क फेज-3, कर्कापट्टा विलेज, मरुकूक मंडल, सिदीपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatla Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

The details of the **original product** manufactured by us is given below:

Product : Rabies Vaccine, Human (Abhayrab)
Batch No. : KA24014
Manufacturing Date : 03/24
Expiry Date : 02/27
MRP : 397.62

Diluent Information : Sodium Chloride Injection 0.9% w/v

Batch No. : SCSVIA3123
Manufacturing Date : 11/23
Expiry Date : 10/27

Photographs of the Original Product:



संघ: सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज 3, काराकपट्टा विलेज, मार्कुक मंडल, सिद्धिपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

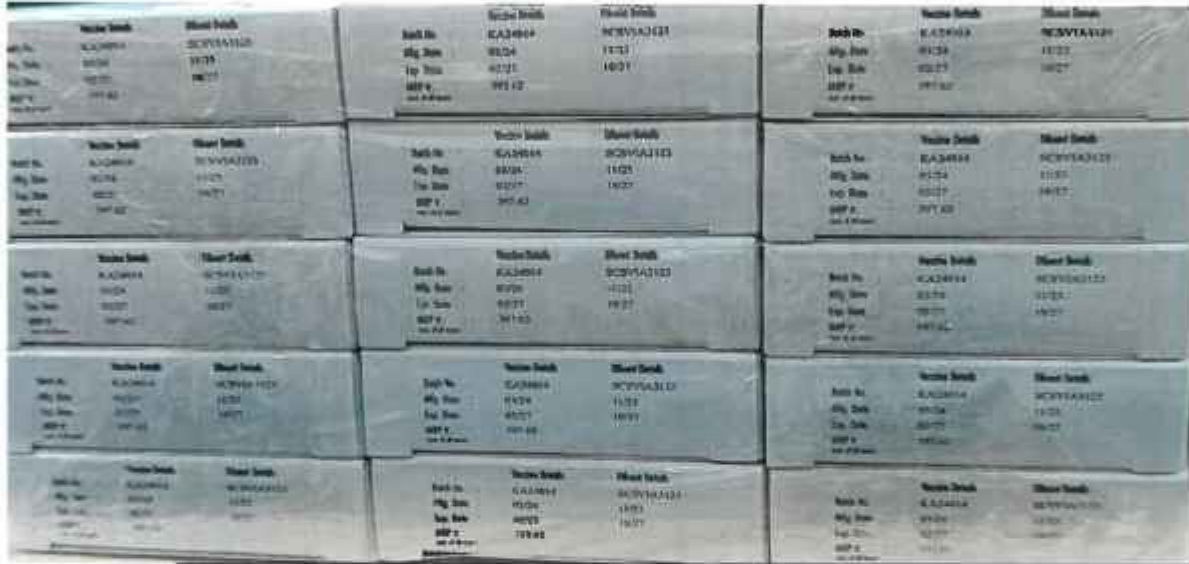
Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)



To assist in addressing this issue, we are providing information about counterfeit product, which come to our notice including batch numbers, manufacturing details, and packaging variations observed in the counterfeit products.

Counterfeit Product Pack-1



संकेत : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज-3, कारकापट्टा विलेज, मार्कुक मंडल, सिद्धिपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)



Rabies Vaccine, Human I.P. -Abhayrab-PF
Counterfeit Product



Rabies Vaccine, Human IP -Abhayrab-PF
The original product which is being manufactured by
HBI (a division of Indian Immunologicals Limited)

The following variation is observed between the original product and the counterfeit product with respect to manufacturing details and packaging variations on the counterfeit product in the above image:

संकेत : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज-3, काराकपट्टा विलेज, मार्कुक मंडल, सिद्धीपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

Product: Rabies Vaccine, Human (Abhayrab)

	Original Product	Counterfeit Product	Variation
Batch No.	KA24014	KA24014	The batch number was allotted to the vaccine with a preservative, but the counterfeit product shows that it is preservative-free. Human Biologicals Institute (a division of Indian Immunologicals) has never produced a Rabies Vaccine, Human (Abhayrab) PF, with this batch number.
Mfg. Date	03/24	03/24	Mfg. date was allotted to with preservative vaccine.
Exp. Date	02/27	02/27	Exp. date was allotted to with preservative vaccine.
Product	Contains preservative	Mono cartons and labels indicate it does not have preservative.	Does not match with the product manufactured by Human Biologicals Institute (a division of Indian Immunologicals)
MRP	397.62	398.40	Old MRP printed (2022)
Flip off seals	Blue	Blue	The Human Biological Institute uses the pink colour seal for the Rabies Vaccine, Human (Abhayrab) PF.
Mono carton	Rabies Vaccine, Human (Abhayrab) (With preservative)	Rabies Vaccine, Human (Abhayrab) PF (PF indicates vaccine is preservative free)	For the Rabies Vaccine, Human (Abhayrab) PF, the batch number series begins with KJ, but the batch number printed on the mono carton begins with the KA series, which indicates that the product contains a preservative (thiomersal).
	The composition contains information about the preservative (thiomersal)	There is no information about preservatives; however, the leaflets inside the containing information about preservative/ thiomersal	Leaflets inside the pack indicates it contains preservative

संकेत : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज-3, काराकपट्टा विलेज, मार्कुकु मंडल, सिद्धिपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

	Original Product	Counterfeit Product	Variation
Printed packaging Materials	-	The printing colour and text on the mono carton, leaflet and vial labels do not match the original label used by the Institute of Human Biologicals Institute (a division of the Indian Institute of Immunology).	Several variations were recorded, mainly: Mono carton- Font size, colour scheme, additional space between printed matters (brand name, etc., batch details and diluent details, product batch number, logo colour). Vial- Seal colour, product batch number, font size, colour variations, etc. Diluent- Warning- Lot to be frozen is mentioned instead of not to be frozen. Leaflet —It is printed in black instead of blue. The font size and artwork number do not match. The reference section information does not match. Reconstitution information with 0.5 mL and 1.0 mL is provided for IM/ID uses, but this product should be reconstituted with 0.5 mL diluent for IM use only.

Counterfeit Product Pack-2



संयंत्र : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेस-3, कारकापट्टा विलेज, मार्कुक मंडल, सिद्दीपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com

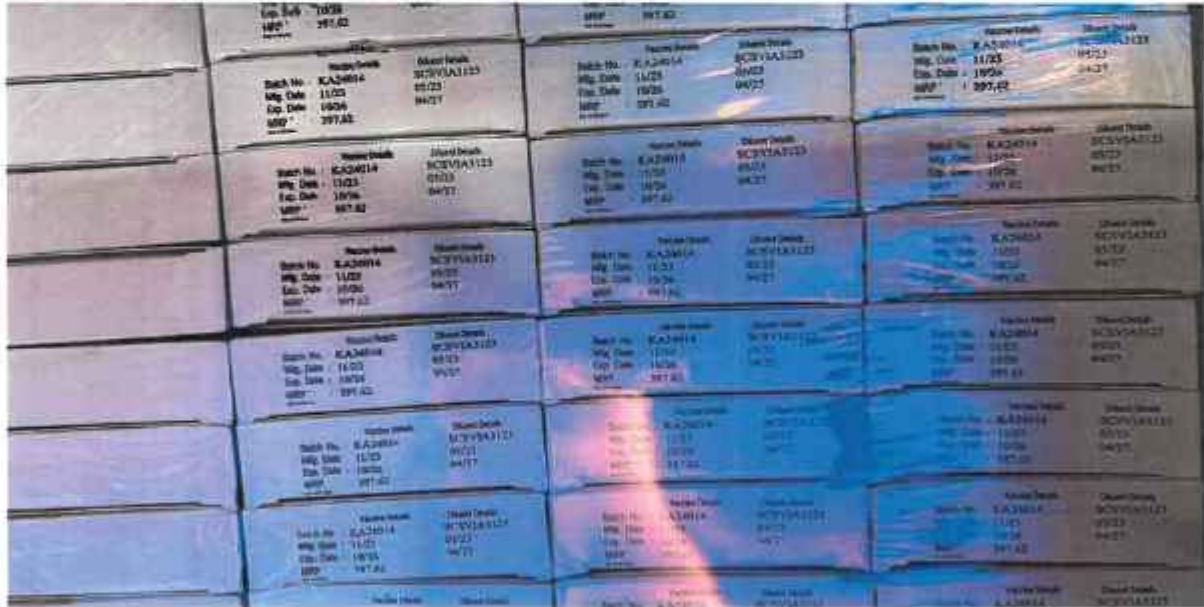


इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्यूमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

1. Rabies Vaccine, Human, Batch No. KA24014 was manufactured and supplied to the retail domestic market with a **green flip-off seal**, but in the above image, the **flip-off seal is blue**.
2. The company does not supply in the packaging configuration shown in the picture above for the retail domestic market. We are supplying only a single vial with its diluent for IM/ID use in mono cartons.
3. However, Rabies Vaccine, Human, for institutional supply, is supplied in multi-carton packs with blue flip-off seals bearing the words "GOVT SUPPLY" on top.

Counterfeit Product Pack-3



The following variations are observed between the original product and the counterfeit product with respect to manufacturing details and packaging variations on the counterfeit product in the above image:

संकेत : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज-3, कारकापट्टा विलेज, मार्कुक मंडल, सिद्धिपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200



CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

Product: Rabies Vaccine, Human (Abhayrab)

	Original Product	Counterfeit Product	Variation
Batch No.	KA24014	KA24014	No variation
Mfg. Date	03/24	11/23	Manufacturing date does not match
Exp. Date	02/27	10/26	Expiry date does not match
MRP			₹ Symbol is missing in counterfeit product
Font	-	-	Printing font is different

Diluent: Sodium Chloride Injection 0.9% w/v

	Original Product	Counterfeit Product	Variation
Batch No.	SCSVIA3123	SCSVIA3123	No variation
Mfg. Date	11/23	05/23	Manufacturing date does not match
Exp. Date	10/27	04/27	Expiry date does not match
Font	-	-	Printing font is different

We hereby request your immediate attention on this matter to help prevent further distribution of these counterfeit product and protect the public from any potential harm. We also urge the CDSCO to investigate the matter thoroughly and take appropriate actions, including:

- Conducting market surveillance to identify and seize counterfeit product.
- Coordinating with law enforcement agencies to identify and prosecute the parties responsible for producing and distributing counterfeit products.

As a responsible manufacturer, we are committed to ensure the safety, quality, and integrity of our products. We remain available to cooperate fully with your team to address this serious issue and take all necessary measures to protect consumers.

संखं : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज-3, कारकापट्टा विलेज, मार्कुक मंडल, सिद्धिपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatla Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नं. 44, जूबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com



इंडियन इम्यूनोलॉजिकल्स लिमिटेड
INDIAN IMMUNOLOGICALS LIMITED

ह्युमन बायोलॉजिकल्स इंस्टिट्यूट
HUMAN BIOLOGICALS INSTITUTE
(A division of Indian Immunologicals Limited)

We appreciate your prompt attention on this matter and look forward for your guidance and assistance in resolving this issue.

Thank you for your support.

Your Sincerely,

Sunil Tiwari

VP & Head of Quality Management

Email: t.sunil@indimmune.com

Mobile: +91-9948036670

For Human Biologicals Institute

(A division of Indian Immunologicals Limited)

संपत्त : सर्वे नं. 281-284 & 321, बायोटेक पार्क फेज-3, कर्कापट्टा विलेज, मरुकुळ मंडल, सिद्दीपेट जिला - 502 281, तेलंगणा, भारत

Plant : Survey No. 281-284 & 321, Biotech Park Phase-3, Karakapatta Village, Markook Mandal, Siddipet Dist - 502 281, Telangana, India.

पंजीकृत कार्यालय : रोड नंबर. 44, जुबिली हिल्स, हैदराबाद - 500 033 तेलंगणा, भारत • दूरभाष : +91-8466924444, +91-7997915555, 040-67682200

Regd. Office : Road No. 44, Jubilee Hills, Hyderabad - 500 033, Telangana, India. • Phones : +91-8466924444, +91-7997915555, 040-67682200

CIN: U72200TG1999PLC032666 • Website : www.indimmune.com • E-mail : info@indimmune.com