

PUBLIC NOTICE

Drug Regulatory and Law Enforcement Agencies Intensify Coordinated Action Against Illegal Manufacture and Distribution of Misbranded Drugs

New Delhi, September 5, 2026

Drug regulatory and law enforcement agencies are maintaining strict and continuous surveillance against illegal manufacture, distribution and supply of misbranded and spurious drugs, with coordinated action being undertaken to identify and disrupt unauthorized drug supply networks and safeguard the quality and safety of medicines available to the public.

The Crime Branch of Delhi Police has been undertaking continuous surveillance to identify criminal activities related to the manufacture and distribution of misbranded and spurious drugs. The Central Drugs Standard Control Organisation (CDSCO) works in close coordination with Delhi Police and other enforcement agencies whenever leads relating to such criminal activity emerge.

As part of this continuing surveillance and enforcement activity, on 22 April 2026, the Crime Branch, Delhi Police, along with a team of Drugs Inspectors from the Drugs Control Department, Government of NCT of Delhi, conducted a search at an unlicensed premises at Flat No. 20/7, Indra Vikas, Second Floor, Mukherjee Nagar, Delhi – 110009. During the search, Rabies Vaccine (Abhayrab); Batch No.KE25012, which was subsequently found to be misbranded (not manufactured by Indian Immunologicals Ltd.), was seized from the premises.

CDSCO officials were called to the premises for legal sampling of the vaccine. The samples were forwarded to the Central Drugs Laboratory (CDL), Kasauli, the Government vaccine testing laboratory, for examination. The product was subsequently reported as misbranded and Not of Standard Quality by CDL, Kasauli.

The laboratory findings, including the specific particulars of the misbranding observed in the seized product, were communicated by the office of the Drugs Controller General (India) (DCGI) to the States/UTs for necessary regulatory vigilance and action.

Through a communication dated 27 August 2026, the DCGI requested all State Drugs Controllers to alert their inspectorate staff and maintain strict vigilance over the movement, distribution and availability of the above-mentioned batch of

the drug. The State Drug Control authorities were also requested to take appropriate regulatory action, as deemed necessary, in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder. The communication to the States also enumerated the relevant details regarding the misbranding of the seized product, as established through laboratory examination.

As a precautionary measure and to ensure that accurate information was available to the public, the manufacturer of Abhayrab also issued a public communication providing the facts concerning the misbranded product. The manufacturer has reaffirmed its commitment towards maintaining the highest standards of quality in the manufacture and supply of its vaccines.

The manufacturer has further stated that every batch of Abhayrab is released for sale only after independent testing and batch-release certification by the Government vaccine testing laboratory, CDL, Kasauli. Vaccines administered at hospitals, clinics and government healthcare facilities, or dispensed through licensed pharmacies, therefore reach patients through the authorized and regulated supply chain, following the prescribed quality-control and batch-release procedures.

It has also been confirmed that no part of the batch concerned was exported to any other country.

The seizure and subsequent regulatory action form part of the ongoing surveillance and enforcement mechanism of drug regulatory and law enforcement agencies to detect unauthorized manufacturing and distribution activities and prevent the circulation of misbranded and spurious medicines.

The coordinated efforts of the CDSCO, State Drug Control authorities, Drugs Control Department, GNCTD and law enforcement agencies demonstrate the continuous vigilance and integrated enforcement mechanism in place to protect public health and ensure that medicines and vaccines available to the public meet the prescribed standards of quality and safety.

In connection with the case, a total of four persons have been arrested by the Delhi Police. Further investigation and appropriate legal action are being undertaken by the competent authorities.

Attachments :

राजकीय विश्लेषक द्वारा किए गए परीक्षण या विश्लेषण का प्रमाण -पत्र

CERTIFICATE OF TEST OR ANALYSIS BY THE GOVERNMENT ANALYST

1. उस निरीक्षक का नाम जिससे प्राप्त हुआ
Name of Inspector from whom received
**Mr. P.Selvaraj, Drugs Inspector
CDSCO, North Zone, C.G.O Building-I
Ministry of Health & Family Welfare
Govt. Of India, Kamla Nehru Nagar,
Hapur Chungi Ghaziabad-201002(U.P).**
2. निरीक्षक के ज्ञापन की क्रम संख्या और तारीख
Serial No. and date of Inspector's Memorandum
NZ/SMP/PS-A/013/2026/466-67 Dt. 23.04.2026
3. नमूनों की संख्या
Number of sample's
30 Vials X 0.5 ml
4. प्राप्ति की तारीख
Date of receipt
11/05/2026
5. नमूने में मालूम होने वाली औषधि का नाम
Name of drugs purporting to be Contained in the sample
**Rabies Vaccine Human ,IP, (Purified Vero Cell
RabiesVaccine), Brand Name:Abhayrab®
Vaccine Batch Details:
Batch No. KE25012 CDL No. 2932/2026 Mfd. date:
08/2025, Exp. Date: 07/2028
Diluent Batch Details:
Batch No.: IVK5010, Mfg. Date: 05/25, Exp. Date:
04/29
Pack Storage: Store at 2°C to 8°C , do not freeze
However, stored at Room Temperature while collecting
sample.
Labelled as Manufactured in India by:
Human Biologicals Institute (A division of Indian
Immunologicals Limited) Sy.no. 281-284 and 321,
Biotech Park, Phase-III, Karkapatla Village, Markook
Mandal, Siddipet (Dist) 502281, Telangana, India.
Pack Size: 1 shrink-wrapped pack of each 15 carton
contains 0.5 ml vial & 0.5 ml water of injection
ampoules.**
6. बंदलों आदि की मोहरें ठीक हैं या नहीं
Condition of seals on the
[Packet or on portion of sample or container]
Intact & comparable with specimen seal
7. परीक्षण या विश्लेषण का परिणाम तथा किए गए परीक्षणों की प्रमाणिता
Result of test or analysis with protocols of tests or analysis applied
As per I.P.
8. मेरा विचार है कि औषधि अधिनियम 1940 और उसके नियमों में की गयी परिभाषा अनुसार नमूना मानक कोटी का नहीं है क्योंकि (कारण):

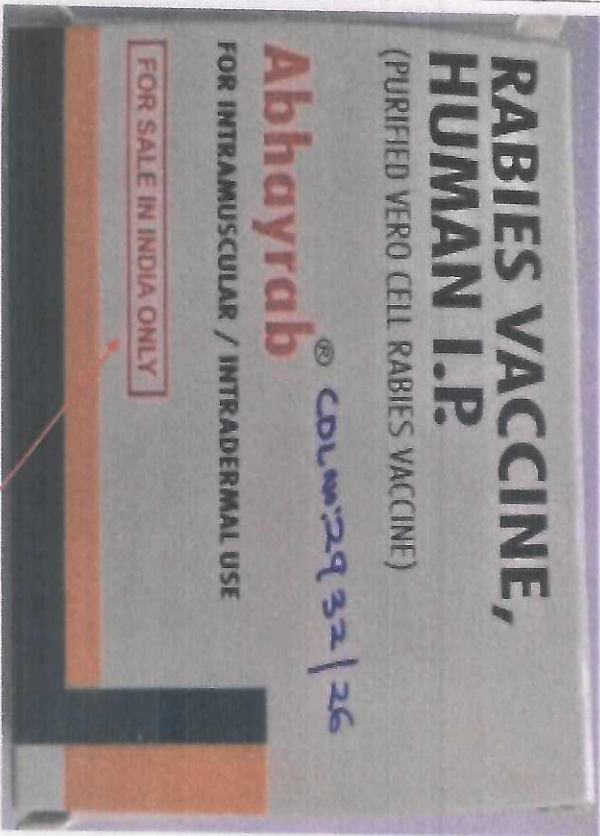
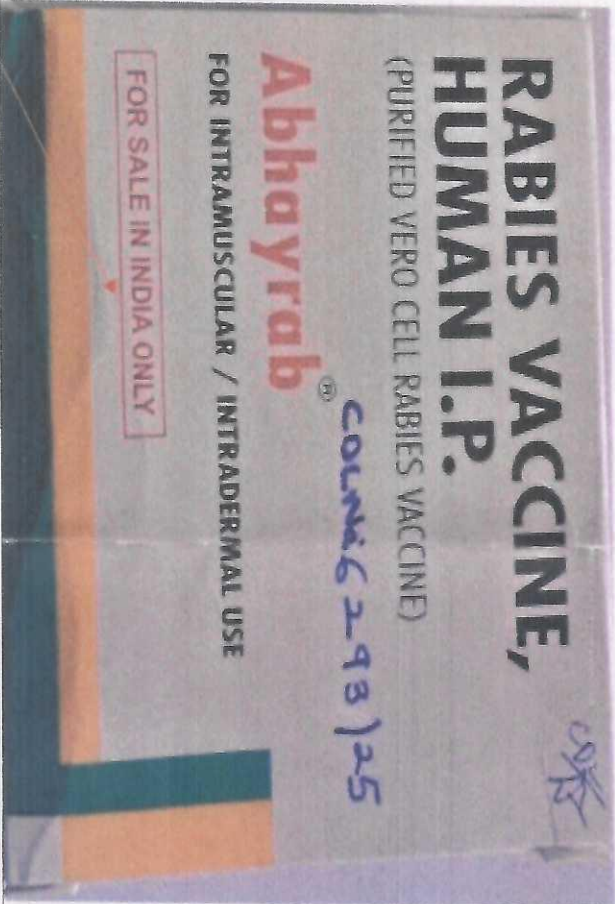
In the opinion of the undersigned, the sample referred above is of **Not of Standard Quality and Misbranded Drug** as per the section 17 as defined in the Drugs and Cosmetics Act, 1940, and 1945 rules there under/ in the tests mentioned below. It is advised that further investigation may be carried to verify the section 17B for spurious drug as per Drugs and Cosmetics Act, 1940, and 1945 rules.

S.NO.	Name of Test	Test Results
1	(भौतिक स्वरूप) Physical aspects	(अनुरूप) Complies
2	(लेबल समीक्षा) Label Review	अनुरूप नहीं है /Does not complies In the label review following observation were observed: 1) The art work of the Rabies Vaccine for batch no.KE25012 submitted by DI on 11/05/2026 does not match with the retained sample of the same batch which was earlier received by this Lab from the firm M/s Human Biologicals Institute, Telangana, for test and analysis on dated 30/09/2025 & released on dated 07/11/2025 vide dispatch no. CDL/2025/8392. 2) In the product name after Rabies Vaccine there is Apostrophe (') comma In sample submitted by DI whereas in the retained sample there is a Comma (,) after product name. 3) After trade name i.e. Abhayrab the size and position of ® symbol is different, in DI submitted the size of ® is large and in retained samples ® is small and position is different. 4) The spelling of L.Pasteur in DI sample is L.Posteur. 5) The concentration of preservative in DI sample is represented as ≤ 0.015 % w/w whereas in retained sample it is as ≤ 0.015 % w/v. 6) In DI sample the diluent concentration is represented as 0.9%w/w and 0.9% w/v in retained sample. 7) Text in warning box is not matching. 8) Colour and style of company's logo is different. 9) Art work number is different, in DI sample it is PLM0395/07/22 and in Retained sample it is PLM0395/08/24. 10) QR code in DI sample not verified by GS1 but in retained sample it is verified by GS1. 11) Text alignment is different. 12) In DI sample Diluent Mfg. Lic. No. is DD/449 but in retained sample it is 30/MD/AP/2013/F/G. 13) Font is different for batch coding details (KE25012,08/25,07/28; IVK5010,05/25/04/29). 14) There is a difference in cap color. The blue cap vial is submitted by DI and Green Color cap is of retained sample in CDL. 15) Font is different. 16) Hologram pasted on seal of blue cap submitted by DI and no hologram is pasted on CDL retained samples. 17) Font and space alignment is also different in both the vials.
3	(विसंक्रमणता) Sterility Test	(पास) Passes
4	(नमी की मात्रा) Moisture Content	(पास) Passes
5	(थायोमर्सल परीक्षण) Thiomersal Test	(पास) Passes
6	(प्रभावशीलता) Potency Test	(विफल)/Fail
7	(पहचान परीक्षण) Identity Test	(पास) Passes

Note: The detail comparison of label review of the sample submitted by DI received at CDL on dt. 11.05.2026 with already retained sample portion of same batch vaccine received at CDL on 30.09.2025 vide CDL No. 6293/2025 submitted by Human Biologicals Institute (A division of Indian Immunologicals Limited) Telangana, India for lot release is attached as **Annexure-I**.

केन्द्रीय औषधि प्रयोगशाला/ Central Drugs Laboratory
कसौली, तिथि/Kasauli, Dated 10.08.2026
संख्या/ ULR No.TC1793426000002932P

राजकीय विश्लेषक, / Government Analyst
केन्द्रीय औषधि प्रयोगशाला/ Central Drugs Laboratory
सरकारी विश्लेषक, Govt. Analyst
केन्द्रीय औषधि प्रयोगशाला, कसौली (हि.प्र.)
Central Drugs Laboratory, Kasauli (H.P.)

S. No.	Drug Inspector Sample	CDL Retained Sample
1	<u>Front & Back View of the outer carton</u> 	<u>Front & Back View of the outer carton</u> 
	Difference Observed between sample received by Drug Inspector and the retained sample on the outer carton, 1. The Font style and size is different in the DI sample as compared with the retained sample. 2. The sample submitted by DI in which "For Sale IN India ONLY" is written in orange font colour whereas in the retained sample in CDL it is written in red font colour.	

Shraddha
10/02/26

RABIES VACCINE, HUMAN I.P.
(PURIFIED VERO CELL RABIES VACCINE)
Abhayrab

Composition:
Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells), Inactivated.
Potency: ≥ 2.5 IU per vial. Stabilizers: Maltose and Human Albumin, q.s.
Preservative: Thimerosal $\leq 0.015\%$ w/w

Reconstitution:
Reconstitute the freeze dried vaccine with 0.5ml diluent (0.9% w/w Sodium Chloride Inj. I.P.) provided along with this pack.
Use immediately after reconstitution.
Refer literature for Dosage, Administration & further information.

Store at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ Do not freeze.

Caution: Do not use if any particulate matter is observed after reconstitution.

Manufactured and Marketed by:
Human Biologics Institute
(A division of Indian Immunologicals Limited)
Survey No. 281/284 and 321, Biotech Park, Phase-III, Kakapudi Village,
Markandeya, Saktipet (Dist.) - 502 281, Telangana, India.
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PLM0395/07/22

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PLM0395/08/24

Difference Observed: In the back side of carton

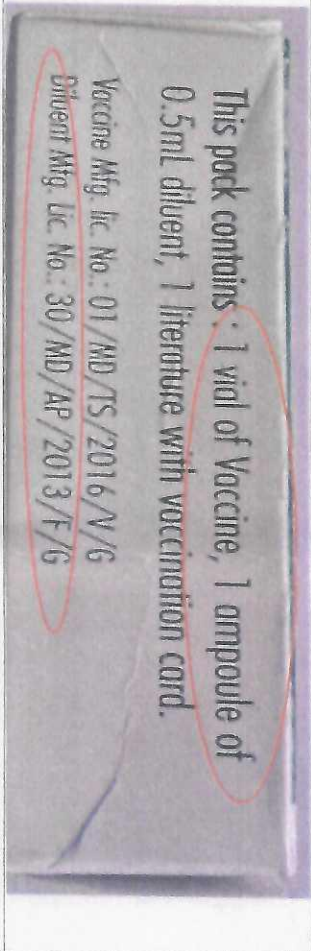
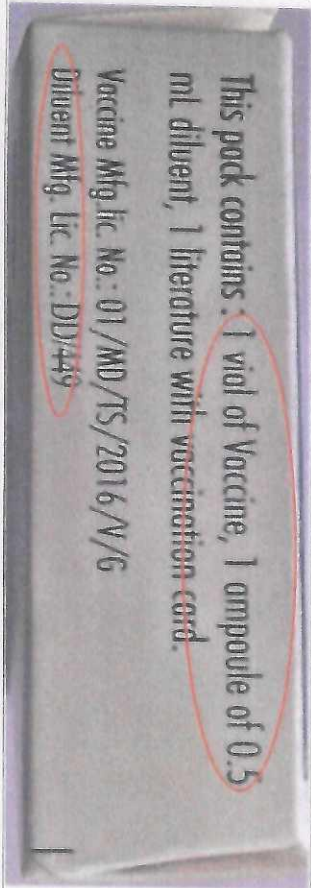
1. In the product name after Rabies Vaccine there is apostrophe comma in sample submitted by DI whereas in the retained sample there is a comma after product name.
2. After trade name i.e. Abhayrab the size and position of ® symbol is different, in DI submitted the size of ® is large and in retained samples ® is small and position is different.
3. The spelling of L. Pasteur in DI sample is L. Pasteur.
4. The concentration of preservative in DI sample is represented as $\leq 0.015\%$ w/w whereas in retained sample it is as $\leq 0.015\%$ w/v.
5. In DI sample the diluent concentration is represented as 0.9%w/w and 0.9%w/v in retained sample.
6. Text in warning box is not matching.
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3



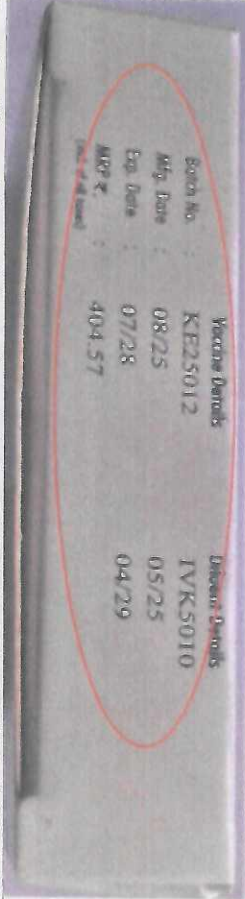
- 1) QR code in DI sample not verified by GS1 but in retained sample it is verified by GS1.
- 2) Font is different.

4



- 1) Text alignment is different.
- 2) In DI sample Diluent Mfg. Lic. No. is DD/449 but in retained sample it is 30/MD/AP/2013/F/G.

5



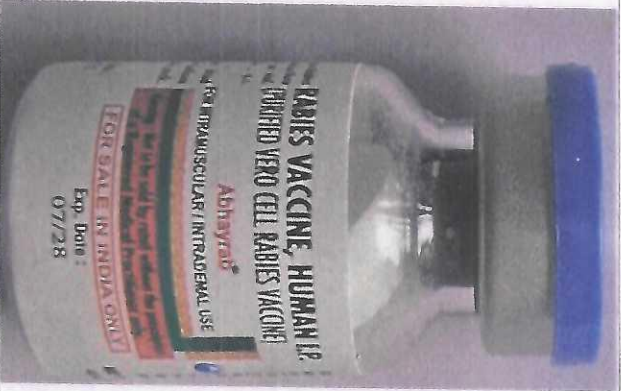
Font is different for batch coding details (KE25012, 08/25, 07/28, IVK5010, 05/25/04/29).

Shades
 10/8/26

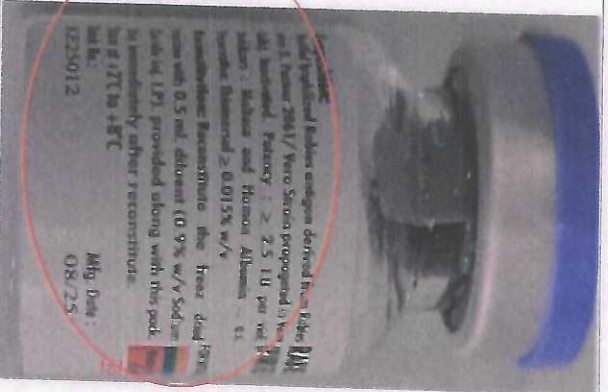
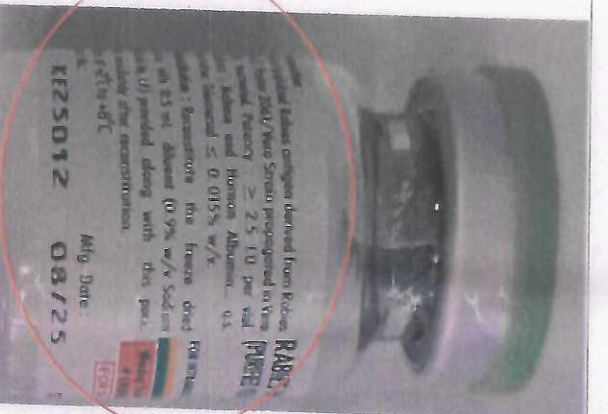
6		
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There is a difference in cap color. The blue cap vial is submitted by DI and Green Color cap is of retained sample in CDL.

Page 4 of 6

7 	
8 Font is different. 	
Hologram pasted on seal of blue cap submitted by DI and no hologram is pasted on CDL retained samples.	

Shree
16/12/26

9 	
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Font and space alignment is also different in both the vials.

Shroff
10/08/26
 SUMIT RA BHALLA
 Senior Software QA Analyst
 Quality Assurance Department (QA)
 Central Drugs Laboratory, Kasauli (H.P.)