



# SERUM INSTITUTE OF INDIA PVT. LTD.

REGD. OFFICE & LABORATORIES : 212/2, HADAPSAR, PUNE - 411028, INDIA

■ TEL.: (Gen) +91-20-2699 3900/ (Dir) +91-20-2660 2379/96 ■ Website : www.seruminstitute.com

■ FAX : (Gen) +91-20-2699 3921/ (Dir) +91-20-2699 3945

## CERTIFICATE OF ANALYSIS

Item Desc :Diphtheria, Tetanus, Pertussis, Hepatitis-B and Hib Vaccine Adsorbed

Batch No :2854X035C  
Quantity : 200238 EA  
Cert.Date :03.12.2024

Mfg. Date :Sep 2024  
Exp. Date :Feb 2027

### Details of labelled Product:

Item No :V285WA12  
Insp Lot No :040000558000  
Date of Lot Cr :24.10.2024

Sampled By :AAM  
Sampling Date :24.10.2024  
Qty for Analysis :8 EA

### Details of unlabelled Product:

Item No :U285V000  
Insp Lot No :040000553803  
Date of Lot Cr :18.09.2024

Sampled By :SAC  
Sampling Date :23.09.2024  
Qty for Analysis :218 EA

### TESTS PERFORMED ON LABELLED PRODUCT:

TEST NAME	SPECIFICATION/ACCEPTANCE CRITERIA	RESULT	REMARKS
IDENTIFICATION - DIPHTHERIA COMPONENT	THE CLEAR SUPERNATANT LIQUID SHALL REACT WITH A SUITABLE DIPHTHERIA ANTITOXIN AND YIELDS A PRECIPITATES/FLOCCULES.	FORMATION OF FLOCCULES.	COMPLIES
IDENTIFICATION - TETANUS COMPONENT	THE CLEAR SUPERNATANT LIQUID SHALL REACT WITH A SUITABLE TETANUS ANTITOXIN AND YIELDS A PRECIPITATION LINE	FORMATION OF PRECIPITATION LINE.	COMPLIES
IDENTIFICATION - PERTUSSIS COMPONENT	TO A SUSPENSION OF SEDIMENT IN SALINE SOLUTION ADD A SUITABLE B.PERTUSSIS ANTISERUM; AGGLUTINATION INDICATES PRESENCE OF PERTUSSIS COMPONENT.	AGGLUTINATION OBSERVED.	COMPLIES
IDENTIFICATION - HEPATITIS-B COMPONENT	VACCINE SHOULD SHOW POSITIVE REACTION FOR HBSAG IN ELISA	POSITIVE REACTION FOR HBSAG IN ELISA.	COMPLIES
IDENTIFICATION - HIB COMPONENT	POSITIVE AGGLUTINATION REACTION.	POSITIVE AGGLUTINATION REACTION	COMPLIES
PHYSICAL INSPECTION - DESCRIPTION	WHITISH TURBID LIQUID (FILLED IN CLEAR GLASS VIAL CLOSED WITH A RUBBER CLOSURE, ALUMINIUM SEAL AND A VIOLET COLOURED FLIP OFF CAP), IN WHICH THE MINERAL CARRIER TENDS TO SETTLE DOWN SLOWLY ON KEEPING AND IS FREE FROM FOREIGN PARTICLES / FLOCCULES.	WHITISH TURBID LIQUID (FILLED IN CLEAR GLASS VIAL CLOSED WITH A RUBBER CLOSURE, ALUMINIUM SEAL AND VIOLET COLOURED FLIP OFF CAP) IN WHICH THE	COMPLIES



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		MINERAL CARRIER TENDS TO SETTLE DOWN SLOWLY ON KEEPING AND IS FREE FROM FOREIGN PARTICLES/FLOCCULES.	
PHYSICAL INSPECTION - VISUAL IDENTIFICATION	CONFIRMATION OF FOLLOWING PARAMETERS ON THE LABEL AND CARTON NAME OF THE PRODUCT, BATCH NO., MANUFACTURING DATE, EXPIRY DATE, LICENSE NO., REGULATORY COMPLIANCE (I.P., B.P. E.P., WHO. OR ANY OTHER REQUIREMENT), SIZE / PRESENTATION.	PASSES	COMPLIES

### TESTS PERFORMED ON UNLABELLED PRODUCT:

TEST NAME	SPECIFICATION/ACCEPTANCE CRITERIA	RESULT	REMARKS
APPEARANCE / DESCRIPTION	WHITISH TURBID LIQUID (FILLED IN CLEAR GLASS VIAL, CLOSED WITH A RUBBER CLOSURE, ALUMINIUM SEAL AND A VIOLET COLOURED FLIP OFF CAP) IN WHICH THE MINERAL CARRIER TENDS TO SETTLE DOWN SLOWLY ON KEEPING AND IS FREE FROM FOREIGN PARTICLES FLOCCULES.	WHITISH TURBID LIQUID (FILLED IN CLEAR GLASS VIAL CLOSED WITH A RUBBER CLOSURE, ALUMINIUM SEAL AND VIOLET COLOURED FLIP OFF CAP) IN WHICH THE MINERAL CARRIER TENDS TO SETTLE DOWN SLOWLY ON KEEPING AND IS FREE FROM FOREIGN PARTICLES/FLOCCULES.	COMPLIES
IDENTIFICATION - DIPHtheria COMPONENT	THE CLEAR SUPERNATANT LIQUID SHALL REACT WITH A SUITABLE DIPHtheria ANTITOXIN AND YIELDS A PRECIPITATES/FLOCCULES.	FORMATION OF FLOCCULES.	COMPLIES
IDENTIFICATION	THE CLEAR SUPERNATANT LIQUID SHALL	FORMATION OF	COMPLIES



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TEST NAME	SPECIFICATION/ACCEPTANCE CRITERIA	RESULT	REMARKS
- TETANUS COMPONENT	REACT WITH A SUITABLE TETANUS ANTITOXIN AND YIELDS A PRECIPITATION LINE	PRECIPITATION LINE.	
IDENTIFICATION - PERTUSSIS COMPONENT.	TO A SUSPENSION OF THE SEDIMENT IN SALINE SOLUTION ADD A SUITABLE B. PERTUSSIS ANTISERUM; AGGLUTINATION INDICATES PRESENCE OF PERTUSSIS COMPONENT.	AGGLUTINATION OBSERVED.	COMPLIES
IDENTIFICATION - HEPATITIS-B COMPONENT	VACCINE SHOULD SHOW POSITIVE REACTION FOR HBSAG IN ELISA	POSITIVE REACTION FOR HBSAG IN ELISA.	COMPLIES
IDENTIFICATION - HIB COMPONENT	POSITIVE AGGLUTINATION REACTION.	POSITIVE AGGLUTINATION REACTION	COMPLIES
OSMOLALITY	NOT LESS THAN 0.240 OSMOL / KG	0.301 Osmol/kg	COMPLIES
PH	BETWEEN 6.0 AND 7.0	6.38	COMPLIES
SPECIFIC TOXICITY (PERTUSSIS-MWGT)	THE VACCINE COMPLIES WITH THE TEST IF (A) AT THE END OF 72 HOURS THE TOTAL WEIGHT OF THE MICE IN THE VACCINE GROUP IS NOT LESS THAN THAT PRECEDING THE INJECTION, (B) AT THE END OF 7 DAYS THE AVERAGE INCREASE IN WEIGHT PER MOUSE IN THE VACCINE GROUP IS NOT LESS THAN 60% OF THAT OF PER MOUSE IN THE CONTROL GROUP AND (C) NOT MORE THAN 5% OF THE INOCULATED MICE DIE DURING THE TEST.	PASSES, WEIGHT GAIN = 71%	COMPLIES
THIOMERSAL	THE AMOUNT IS NOT LESS THAN 85 PERCENT AND NOT GREATER THAN 115 PERCENT OF THE LABEL I.E. (0.005% W/V) CLAIM. (0.00425 - 0.00575% W/V).	0.00510 % w/v	COMPLIES



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## CERTIFICATE OF ANALYSIS

Item Desc : Diphtheria, Tetanus, Pertussis, Hepatitis-B and Hib Vaccine Adsorbed

Batch No : 2854X035C  
Quantity : 200238 EA  
Cert.Date : 03.12.2024

Mfg. Date : Sep 2024  
Exp. Date : Feb 2027

### TESTS PERFORMED ON UNLABELLED PRODUCT:

TEST NAME	SPECIFICATION/ACCEPTANCE CRITERIA	RESULT	REMARKS
FREE FORMALDEHYDE	NOT MORE THAN 0.02% W/V FREE FORMALDEHYDE	0.0018 % w/v	COMPLIES
ALUMINIUM CONTENT.	NOT MORE THAN 1.25 MG PER SINGLE HUMAN DOSE	0.2724 mg/SHD	COMPLIES
STERILITY	NO EVIDENCE OF MICROBIAL GROWTH SHOULD BE FOUND.	COMPLIES	COMPLIES
DIPHThERIA COMPONENT (VERO CELL ASSAY).	TEST VACCINE SHOULD SHOW A MEAN ANTI DIPHThERIA SERUM TITER AT A LEVEL EQUAL OR HIGHER THAN STANDARD DIPHThERIA TOXOID USED FOR IMMUNIZATION AT 80IU/ML STRENGTH WHEN TESTED AT 1:5 DILUTION	MORE THAN 40 IU/DOSE. TEST VACCINE SHOWED ANTIBODY TITER HIGHER THAN STANDARD DIPHThERIA TOXOID AT 80 IU/ML WHEN TESTED AT 1:5 DILUTION.	COMPLIES
POTENCY-TETANUS COMPONENT (CHALLENGE METHOD IN MICE)	THE LOWER CONFIDENCE LIMIT (P = 0.95) OF THE ESTIMATED POTENCY IS NOT LESS THAN 60 IU PER SINGLE HUMAN DOSE. HOWEVER INHOUSE RELEASE WITH THE LOWER CONFIDENCE LIMIT (P = 0.95) OF THE ESTIMATED POTENCY IS NOT LESS THAN 200 IU PER SINGLE HUMAN DOSE.	398.898 IU/DOSE 95% CL (323.028-489.088)	COMPLIES
TETANUS COMPONENT (ELISA METHOD)	TEST VACCINE SHOULD SHOW A MEAN ANTI TETANUS SERUM TITER AT A LEVEL EQUAL OR HIGHER THAN STANDARD TETANUS TOXOID USED FOR IMMUNIZATION AT 100 IU/ML STRENGTH WHEN TESTED AT 1:5 DILUTION.	MORE THAN 50 IU/DOSE. TEST VACCINE SHOWED ANTIBODY TITER HIGHER THAN STANDARD TETANUS TOXOID AT 100 IU/ML WHEN TESTED AT 1:5 DILUTION.	COMPLIES
POTENCY-PERTUSSIS	THE VACCINE PASSES THE REQUIREMENT FOR POTENCY IF THE RESULT OF A	5.6206 IU/DOSE, 95% CL (3.1889-9.9592)	COMPLIES



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COMPONENT (IN MICE )	STATISTICALLY VALID TEST SHOWS THAT THE ESTIMATED POTENCY OF THE VACCINE IS NOT LESS THAN 4.0 IU IN THE VOLUME RECOMMENDED FOR THE SINGLE HUMAN DOSE AND IF THE LOWER FIDUCIAL LIMIT (P = 0.95) OF THE ESTIMATED POTENCY IS NOT LESS THAN 2.0 IU		
POTENCY - HEPATITIS B (IN-VITRO)	THE HBSAG CONTENT OF THE TEST VACCINE SHOULD BE NOT LESS THAN 20 $\mu$ G/ML OR 10 $\mu$ G/SHD	50.267 $\mu$ G/ML 95% CL(42.465-60.526)	COMPLIES
POTENCY - HIB PRP CONTENT (TOTAL PRP)	SHALL BE WITHIN 80 - 120 % OF THE ADDED QUANTITY (8 - 12 $\mu$ G/DOSE)	8 MCG/0.5ML	COMPLIES
POTENCY - HIB PRP CONTENT (FREE PRP)	NOT MORE THAN 30 % OF TOTAL PRP CONTENT.	6 %	COMPLIES
EXTRACTABLE VOLUME	SINGLE DOSE CONTAINERS (AMPOULES OR VIALS WITH NOMINAL VOLUME OF 2 ML OR LESS): THE VOLUME IS NOT LESS THAN THE NOMINAL VOLUME IN CASE OF CONTAINERS EXAMINED INDIVIDUALLY AND THE POOLED CONTENT OF FIVE CONTAINERS IS NOT LESS THAN THE SUM OF THE NOMINAL VOLUME OF THE CONTAINERS TAKEN COLLECTIVELY.	THE VOLUME IS NOT LESS THAN THE NOMINAL VOLUME IN CASE OF CONTAINERS EXAMINED INDIVIDUALLY AND THE POOLED CONTENT OF FIVE CONTAINERS IS NOT LESS THAN THE SUM OF NOMINAL VOLUME OF THE CONTAINERS TAKEN COLLECTIVELY.	COMPLIES
HOMOGENEITY TEST	THE ALUMINIUM CONTENT OF SUB LOT SHOULD BE WITHIN + OR - 5 % OF BULK VALUE. NO ANY CLUMPS OR VISIBLE PARTICLE OBSERVED. AFTER SHAKING GEL SHOULD FORM UNIFORM SUSPENSION.	PASSES	COMPLIES
ADSORPTION OF	NLT 40%	89.00 %	COMPLIES



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TEST NAME	SPECIFICATION/ACCEPTANCE CRITERIA	RESULT	REMARKS
DIPHTHERIA COMPONENT (%)			
ADSORPTION OF TETANUS COMPONENT (%)	NOT LESS THAN 40.00%	60.00 %	COMPLIES
ADSORPTION OF HEPATITIS-B COMPONENT (%)	NOT LESS THAN 70.00%	100.00 %	COMPLIES
PARTICULATE MATTER (VISIBLE)	THE PRODUCT FAILS THE TEST IF ONE OR MORE PARTICLES ARE FOUND IN MORE THAN ONE CONTAINER.	PARTICULATE MATTER IS NOT OBSERVED.	COMPLIES
CONTAINER CLOSURE INTEGRITY	NO COLOUR CHANGE OF THE SAMPLE SOLUTION SHOULD BE OBSERVED.	NO COLOUR CHANGE OF THE SAMPLE SOLUTION IS OBSERVED.	COMPLIES
BACTERIAL ENDOTOXIN	ACTUAL VALUE.	88566.4250 EU/SHD	COMPLIES

PRODUCT COMPLIES AS PER WHO SPECIFICATION WITH RESPECT TO ABOVE TESTS

Analysed by:

Checked by:

Quality Control In-Charge:

03.12.2024

03.12.2024

J. K. Nay

Date:

Date:

Date:

03/12/24