

Regd.

केन्द्रीय औषधि प्रयोगशाला,
केन्द्रीय अनुसंधान संस्थान,
कसौली, हिमाचल प्रदेश - 173204
फैक्स/0091-1792-272049 - 272016
दूरभाष/ : 0091-1792-272578-272046
मेल : nclkasauli@gmail.com
cdlkasauli@cdsco.nic.in



Central Drugs Laboratory,
Central Research Institute,
Kasauli, Himachal Pradesh-173204
Fax: 0091-1792-272049 -272016
Tel: 0091 -1792-272578 -272046
email id: nclkasauli@gmail.com
cdlkasauli@cdsco.nic.in

National Control Laboratory - Batch Release Certificate *By mail*

Trade name	Diphtheria, Tetanus, Pertussis , Hepatitis B and Haemophilus influenzae Type b Conjugate Vaccine Adsorbed			
Non-proprietary name	Diphtheria, Tetanus, Pertussis , Hepatitis B and Haemophilus influenzae Type b Conjugate Vaccine Adsorbed			
Name and Address of Sample sender	Dr.Sunil Gairola, Executive Director, Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, PUNE - 411 028.			
Sample sender's reference and date	SG/CDL/RELEASE/2024/629 dated 06.12.2024			
Type of container	Vial			
Presentation	0.5 ml -1 dose (IM route)			
Prescribed storage temperature	2 ^o C - 8 ^o C			
License Number	Manufacturing License Number: 10			
Supply	EXPORTS			
The following lots of Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus influenzae Type b Conjugate Vaccine Adsorbed , mfd. by Serum Institute of India Private Limited, Pune in India whose numbers appear on the labels of the final containers, meets all national requirements and WHO requirements for Part 'A' for Biological Substances No. 45 (Requirements for Hepatitis-B Vaccine mfd. by Recombinant DNA techniques, published in 2013, Part-A of the Diphtheria-Tetanus and Pertussis Section(s) of the WHO Requirements for Biological Substances No. 8, 10 & 36 (Requirements for Diphtheria, Tetanus, Pertussis and Combined Vaccines, Revised, 2014), Requirements for Biological substances No.46 for Haemophilus type b conjugate vaccine, 2000 and the WHO Requirements for Biological Substances No. 1 (General Requirements for Manufacturing Establishments and Control Laboratories, Revised 1992), are found to be of STANDARD QUALITY and be RELEASED.				
CDL No.	Batch No.	Mfg. Date	Exp. Dt.	Maximum no. of containers & doses for release
7342/2024	2854X035A	SEP-2024	FEB-2027	2,08,921 Vials = 2,08,921 doses
7343/2024	2854X035B	SEP-2024	FEB-2027	2,10,914 Vials = 2,10,914 doses
7344/2024	2854X035C	SEP-2024	FEB-2027	1,95,985 Vials = 1,95,985 doses
7345/2024	2854X035D	SEP-2024	FEB-2027	2,12,164 Vials = 2,12,164 doses
7346/2024	2854X035E	SEP-2024	FEB-2027	2,11,038 Vials = 2,11,038 doses
7347/2024	2854X035F	SEP-2024	FEB-2027	2,12,607 Vials = 2,12,607 doses
7348/2024	2854X035G	SEP-2024	FEB-2027	1,59,088 Vials = 1,59,088 doses

These batches have been examined by CDL using documented procedures which form part of a quality system which is in accordance with the ISO/IEC: 17025 standard. As a minimum, this release is based on scrutiny of summary lot protocols (SLPs) and test results information detailed therein by the manufacturer.

Name of Signatory: SUMIR RAI BHALLA	Certificate Number CDL/2024/ 8761
Designation : GOVERNMENT ANALYST	Date of Release 27/12/24
Signature : 	