

Regd.

केन्द्रीय औषधि प्रयोगशाला,
केन्द्रीय अनुसंधान संस्थान,
कसौली, हिमाचल प्रदेश - 173204
फैक्स/0091-1792-272049 - 272016
दूरभाष/ : 0091-1792-272578-272046
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National Control Laboratory - Batch Release Certificate

FAX COPY

Trade name	Diphtheria and Tetanus Vaccine Adsorbed (Pediatric)
Non-proprietary name	Same as for trade name
Name and Address of Sample sender	Dr.S.S.Jadhav, Executive Director (Q.A.) Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, PUNE-411 028.
Sample sender's reference and date	SSJ/CDL/RELEASE/2019/190 dated 12.04.2019
Type of container	Vial
Presentation	5 ml-10 doses (IM route)
Prescribed storage temperature	2 ⁰ C - 8 ⁰ C
License Number	Manufacturing License Number: 10
Supply	EXPORT

The following lot of Diphtheria and Tetanus Vaccine Adsorbed (Pediatric), 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, Part-A of the Diphtheria-Tetanus Section(s) of the WHO Requirements for Biological Substances No. 8 & 10 (Requirements for Diphtheria, Tetanus, Pertussis and Combined Vaccines, Revised, 2014), and the WHO Requirements for Biological Substances No. 1 (General Requirements for Manufacturing Establishments and Control Laboratories, Revised 1992), is found to be STANDARD QUALITY and be RELEASED.

CDL No.	Batch No.	Mfg. Date	Exp. Dt.	Maximum no. of containers & doses for release
2197/2019	2459L001	FEB-2019	JAN-2022	42,756 Vials = 4,27,560 doses

This batch has 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: Dr. ARUN BHARDWAJ	Certificate Number: CDL/2019/2500
Designation : DIRECTOR	Date of Release 16 MAY 2019
Signature :	

CC: SRM
SDR/ITS/RE/PO/RS
DKS/SG/YS/EST/AL
MM/VS/AD/CA
- YCBhake
17/05/2019