

Certificate No: 07/2026/LR
National Control Laboratory
Medical Research Institute
Colombo 08
27.02.2026

Chief Epidemiologist
Epidemiology Unit
Colombo 10

Release certificate for Diphtheria and Tetanus Vaccine Adsorbed - DT

With reference to your application for lot release of above vaccine dated 24.02.2026, release certificate in respect of Diphtheria and Tetanus Vaccine Adsorbed 5.0 mL (10 doses per vial) Lot No. C2168 and C2169, with dates of expiry December 2027 and February 2028, manufactured by BB-NCIPD EAD, 26 Yanko Sakazov, 1504 Sofia, Bulgaria, is enclosed.

This consignment of Diphtheria and Tetanus Vaccine Adsorbed 5.0 mL (10 doses per vial), has been received as a UNICEF donation. This product which is a WHO prequalified vaccine is not registered in Sri Lanka. NMRA has granted permission under the category of waiver of registration of pharmaceuticals to import and supply and customs clearance of the consignment of the aforesaid product on the request made by the Epidemiology Unit, Ministry of Health, Colombo 10, Sri Lanka. Other necessary documents such as NCL Lot release certificate of manufacturing country, Certificate of Analysis and Summary Lot protocol were available for review.

Considering the country requirement, this batch of Diphtheria and Tetanus vaccine is released for use.


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Dr. M.A.R.V Muthugala
Head NCL

Cc: CEO, National Medicines Regulatory Authority



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மருத்துவ ஆராய்ச்சி நிறுவனம்
MEDICAL RESEARCH INSTITUTE
NATIONAL CONTROL LABORATORY
SRI LANKA



National Control Laboratory – Lot Release Certificate

Examined under the gazette notification No.1052/3 of 02/11/1998 and according to the section 137 (2) of National Medicines Regulatory Authority Act No. 5 of 2015.

Name of the vaccine/serum	Diphtheria and Tetanus Vaccine, Adsorbed
Trade name	Same as above
Name and address of manufacturer	BB-NCIPD EAD, 26 Yanko Sakazov, 1504 Sofia, Bulgaria.
Name and address of sample sender	Chief Epidemiologist, Epidemiology Unit, Colombo 10
Sample sender's reference and date	Documents and Samples submitted on: 26.02.2026
Type of container	5.0 mL Vial
Number of doses per container	10 (0.5 mL/dose)
Prescribed storage temperature	2°C – 8°C

Lot No	Mfg. Date	Exp. Date	No of containers released
C2168	28.01.2025	December 2027	4,820
C2169	25.03.2025	February 2028	10,980

This vaccine / serum lot is in compliance with the specifications approved in the marketing authorization and all national and relevant WHO requirements*, and is released.

This examination is based on

- the review of the manufacturing and testing protocols
 the appropriate control laboratory tests as indicated in the vaccine testing policy

Certificate No: 07/2026/LR	Date of issue: 27.02.2026
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Signature:

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Name and designation of authorized signatory: Dr. M.A.R.V Muthugala, Head / NCL

* WHO Technical Report Series No 986, Annex 2, 2014; WHO Technical Report Series No 999, Annex 2, 2016;
WHO Technical Report Series No 978, Annex 2, 2013; WHO Technical Report Series No 980, Annex 6, 2014

Copy to – CEO, National Medicines Regulatory Authority