

DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TAMILNADU

359, Anna Salai, Chennai - 600 006, Tamil Nadu.

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

[This certificate conforms to the format recommended by the world health organization (general instructions and explanatory notes attached)]

Certificate No: K Dis No: 19992/D1/2/2016, Dated:13 .06.2017

On the basis of the inspection carried out on 10.04.2017 to 12.04.2017 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name and address of site:

M/s. . Human Biologicals Institute, A division of Indian Immunologicals Ltd., Kozhipannai, Pudumund (Po) Udhagamandalam – 643 007.

2 Manufacturer's licence number:

Form 28D Bearing No: 15, Dated 11.01.2000

3 Table 1:

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(Vide List Attached)	ı	
Vaccines		Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 31.12.2019 It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in

compliance with GMP.

Name and function of responsible ber

Place: Chennai Date: 13.06,2017

lephone No. 91-44 2433 5068

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Tamil Nadu.

Fax No.:91-44-2432 1830 S. ABDUL KHADER, B.Pham,

5. ABDUL KHADER, B.Phame, Director of Drugs Control 359, Anna Salai, Ghennal-600 00%.

Email:tndcad@gmail.com

Explanatory notes

- 1) This certificate, which is in the format recommended by WHO, certifies the status of the Site listed in point 1 of the certificate.
- 2) The certification number should be traceable within the regulatory authority issuing the certificate.
- 3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in case where there is no legal framework for the issuing of a licence.
- 4) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
- 5) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

