

Office of The Commissioner, Food & Drugs Administration M.S. Bandra - Kurla Complex, Bandra (E), Mumbai - 400 051 Date :-04 Jul 2022

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.: NEW-WHO-GMP/CERT/KD/107921/2022/11/39826

On the basis of the inspection carried out on 23.12.2021 & 24.12.2021 ,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.

Name of the Firm

BHARAT SERUMS AND VACCINES LIMITED

Address

PLOT NO K-27, K-27 PART AND K-27/1,

ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC, AMBERNATH (EAST), THANE 421506 MAHARASHTRA STATE, INDIA

Licence No. 2.

KD360 In Form 28,

KD4 In Form 28D, KD5 In Form 28E

Table 1

Dosage Form(s)	Categor(ies)	Activity(ies)
Active Pharmaceutical Ingredients (Bulk Drugs)	Anti-sera / Anti-Toxin	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
Active Pharmaceutical Ingredients (Bulk Drugs)	Blood Products	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
Active Pharmaceutical Ingredients (Bulk Drugs)	Hormones	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
Active Pharmaceutical Ingredients (Bulk Drugs)	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
Dry Powder Injections	Blood Products	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
	Active Pharmaceutical Ingredients (Bulk Drugs) Active Pharmaceutical Ingredients (Bulk Drugs)	Active Pharmaceutical Ingredients (Bulk Drugs) Recombinant Vaccines / Drugs

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 29 Mar 2025 . 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.

Address of certifying autis Food & Drug Adminip

Bandra-kurla Com Bandra (E), Murusa Maharashtra, IMM Tel: +91-22-2552363 400 051.

363/64 Fax: +91-22 5591959

AD VACCINES LIMITED BHARAT SERUM NEW-WHO-GMF /39826

ame of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India Date:04 Jul 2022