

Office of The Commissioner. Food & Drugs Administration M.S. Bandra - Kurla Complex, Bandra (E), Mumbai - 400 051 Date :-28 Jun 2024

# 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/137940/2024/11/50748

On the basis of the inspection carried out on 05/06/2024 & 06/06/2024 ,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

RELIANCE LIFE SCIENCES PVT. LTD.

Address

DHIRUBHAI AMBANI LIFE SCIENCES CENTRE,

PLANT 2 & 7 PLOT NO. R-282 TTC AREA OF MIDC, THANE BELAPUR ROAD, RABALE, NAVI MUMBAI THANE 400701 MAHARASHTRA STATE, INDIA

2. Licence No. KD07 In Form 28D

#### Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Injectables	Recombinant Vaccines / Drugs	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
2	Liquid Injection ( SVP )	Recombinant Vaccines / Drugs	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
	Active Pharmaceutical Ingredients ( Bulk Drugs)	Recombinant Vaccines / Drugs	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
4	Lyophilised / Powder injectable	Recombinant Vaccines / Drugs	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance

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 27 Jun 2027. 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 authority Food & Drug Administration, Bandra-kurla Complex,

Bandra (E), Mumbai – 400 Maharashtra, INDIA.

Tel: +91-22-26592363/64 Fax: +91-22-26591959

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RELIANCE LIFE SCIENCES PVT. LTC WHO-GMP/CERT/KD/137940/2024

uthorised person : D. R. GAHANE

Signature:

p and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date:28 Jun 2024

## **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 cases where there is no legal framework for the issuing of a licence.
- 4. Table 1
  List the dosage forms, starting materials, categories and activities. Examples are given below.

### Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		29
Tablets	Cytotoxic	Packaging
	Hormone	Packaging, Quality
Injectables	Penicillin //	Repackaging & Lawling.
***	Cefalosporis	Aseptic preparation thickaging,
8	200	Labeling

#### Example - 2.

Pharmaceutical Product (s)1	Category (18)	Activity (ies)
Starting material (s)2		The state of the s
Paracetamol	Analgesic	Synthesis, Purification,
		Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

- 5. 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.
- 6. The requirements for good practices 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.