महाराष्ट्र शासन
आयुक्त
अन्न वा औषध प्रशासन , महा. राज्य
३४१ , वांद्रे - कुर्ला संकुल , रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.

सत्यमेव जयते
FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/137940/2024/ 2292 /11

दिनांक. 28/06/2024

Digitally signed by Susarencu Svetlana
Date: 2026.06.24 09:23:03 EEST
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प्रति,
RELIANCE LIFE SCIENCES PVT. LTD.
THANE

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 137940

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/137940 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत

आपला

(~~डॉ. सं. ने. काले~~)
सहाय्यक आयुक्त (मुख्यालय) (डेस्क ११)
अन्न व औषध प्रशासन , म. राज्य.

FDA MAHARASHTRA

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.

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
3	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, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
ILER51613794020240628
RELIANCE LIFE SCIENCES PVT. LTD. - NEW-WHO-GMP/CERT/KD/137940/2024/11/50748

Name 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:**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)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
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.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/137940/2024/11/50748 **VALID UP TO :27 Jun 2027**

Name of Manufacturing Firm : RELIANCE LIFE SCIENCES PVT. LTD.
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

Drug License No : KD07 In Form 28D

Sr.No.	Name of the Product	Composition
41	Ranibizumab Injection 0.5 mg dose Combikit	Each Kit contains: Ranibizmnab Injection 0.5 mg dose (Each 0.23 mL in vial contains Ranibizumab 2.30 mg) IHS Disposable Hypodermic Needle (1/2 inch, 30G) (not covered under scope of this certificate) IHS Disposable Hypodermic Needle (1 1/2 inch, 5µ Filter, 18G) (not covered under scope of this certificate) IHS Disposable Hypodermic Syringe (1 mL) (not covered under scope of this certificate) IHS Isopropyl Alcohol Swab (not covered under scope of this certificate) USP
42	Recombinant Follicle Stimulating Hormone (r-FSH) Bulk (Drug substance)	Recombinant Follicle Stimulating Hormone (r-FSH) IH 3.0 mg/ml
43	Recombinant Follicle Stimulating Hormone Injection 1200 IU	Each 1.6 ml in Multidose vial contains Recombinant Follicle Stimulating Hormone (r-FSH) IH 1200 IU Aqueous citrate buffer containing Sucrose Polysorbate 20 L-methionine Benzyl alcohol as preservative
44	Recombinant Follicle Stimulating Hormone Injection 300 IU	Each 0.4 ml in Multidose vial contains Recombinant Follicle Stimulating Hormone (r-FSH) IH 300 IU Aqueous citrate buffer containing Sucrose Polysorbate 20 L-methionine Benzyl alcohol as preservative
45	Recombinant Follicle Stimulating Hormone Injection 900 IU	Each 1.2 ml in multidose vial contains Recombinant Follicle Stimulating Hormone (r-FSH) IH 900 IU Aqueous citrate buffer containing Sucrose Polysorbate 20 L-methionine Benzyl alcohol as preservative
46	Recombinant Human Growth Hormone (Somatropin) drug substance	Each ml contains Recombinant Human Growth Hormone (Somatropin) IH 4.0 to 8.0 mg/ml
47	Recombinant Human Growth Hormone (Somatropin) Injection 5 mg	Each 1.5 ml in vial contains Recombinant Human Growth Hormone (Somatropin) IH 3.33 mg/ml
48	Recombinant Human Interferon alpha 2b Injection 3 MIU	Each 0.5 ml in vial contains Interferon alpha 2b concentrated solution Ph.Eur 3 MIU Aqueous buffer qs

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RELIANCE LIFE SCIENCES PVT. LTD. - NEW-WHO-GMP/CERT/KD/137940/2024/11/50748

Name 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:**28 Jun 2024**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/137940/2024/11/50748 **VALID UP TO :27 Jun 2027**

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DHIRUBHAI AMBANI LIFE SCIENCES CENTRE,
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MUMBAI THANE 400701 MAHARASHTRA STATE,
INDIA

Drug License No : KD07 In Form 28D

Sr.No.	Name of the Product	Composition
49	Recombinant Human Interferon alpha 2b Injection 5 MIU	Each 0.5 ml in vial contains Interferon alpha 2b concentrated solution Ph.Eur 5 MIU Aqueous buffer qs
50	Recombinant Interferon alpha 2b Injection 3 MIU	Each 0.5 ml in vial contains Interferon alpha 2b concentrated solution IP 3 MIU Aqueous buffer qs
51	Recombinant Interferon alpha 2b Injection 5 MIU	Each 0.5 ml in vial contains Interferon alpha 2b concentrated solution IP 5 MIU Aqueous buffer qs
52	Recombinant Interferon beta 1a (Bulk)	Each mL contains Recombinant Interferon beta 1a IH 0.25-1.25 mg/ml
53	Recombinant Interferon Beta 1a Injection	Each 0.5ml in Pre-filled Syringe contains Recombinant Interferon beta 1a IH 30 mcg Sodium acetate trihydrate IH 0.79 mg Glacial acetic acid IH 0.25 mg L-Arginine Hydrochloride IH 15.75 mg Polysorbate 20 IH 0.025 mg Water for Injection IH qs
54	Recombinant Tissue Plasminogen activator (Reteplase) (Bulk)	Recombinant Tissue Plasminogen activator (Reteplase) Bulk IH 1.5 - 5.0 mg/ml
55	Recombinant Tissue Plasminogen Activator (Reteplase) for Injection kit	Each kit Contains Reteplase (Recombinant Tissue Plasminogen Activator) 18 mg 2 ampoules of Sterile Water for Injection USP for reconstitution USP 10 ml 2 single use sterile syringes IH 10 ml 4 Sterile needles IH Aqueous buffer containing sucrose, Tranexamic acid, Polysorbate 80, Potassium Phosphate & Phosphoric acid IH 0 Sterile Needles and Syringes are not covered under the scope of this certification
56	Recombinant Tissue Plasminogen Activator (Reteplase) for Injection Kit	Each kit contains 2 single use Recombinant Tissue Plasminogen Activator (Reteplase) 18 mg (10 units) sterile lyophilized powder IH Other contents; 2 ampoules of 10 ml sterile water for Injection IP for reconstitution (Althea Pharma Private Ltd.) , 2 single use 10 ml sterile syringes, 4 sterile needles Sterile Needles and Syringes are not covered under the scope of this certification

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RELIANCE LIFE SCIENCES PVT. LTD. - NEW-WHO-GMP/CERT/KD/137940/2024/11/50748

Name 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:28 Jun 2024