FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-28 Oct 2021

# 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/106550/2021/11/37729**

On the basis of the inspection carried out on **13/08/2020, 14/08/2020 AND 09/09/2020** ,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 : **SYNGENE INTERNATIONAL LIMITED.**
   Address : **SYNGENE INTERNATIONAL LIMITED. PLOT NO.C/4/10/B/2, 1ST FLOOR,PRINCE PLAZA SHOPPING COMPLEX CENTRE,GIDC AREA, ANKLESHWAR, BHARUCH, ANKLESWAR**
   Manufacturing At : **KAMLA LIFESCIENCES LTD PLOT NO G-84/1 TARAPUR MIDC BOISAR PALGHAR 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **103908A In Form 28A**

Table 1

| Sr.No. | Dosage Form(s) | Categor(ies) | Activity(ies) |
|---|---|---|---|
| 1 | Lyophilised / Powder injectable | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, 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 22 Sep 2023 . 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

1NYS24910655020211028
SYNGENE INTERNATIONAL LIMITED. - NEW-WHO-GMP/CERT/KD/106550/2021/11/37729

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 Oct 2021**

Digitally signed by Harea Stefan
Date: 2021.12.28 12:49:48 EET
Reason: MoldSign Signature
Location: Moldova

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. |

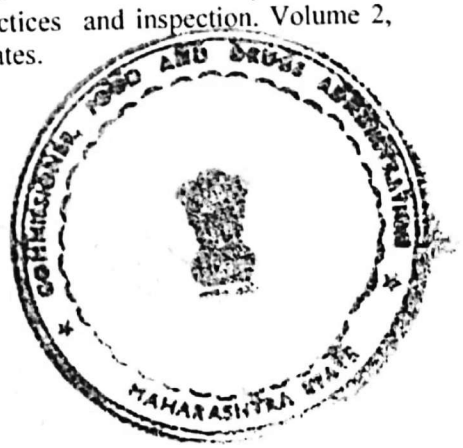
   Example - 2.

| 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/106550/2021/11/37729 **VALID UP TO :22 Sep 2023**

**Name of Manufacturing Firm** : SYNGENE INTERNATIONAL LIMITED.
SYNGENE INTERNATIONAL LIMITED. PLOT NO.C/4/10/B/2, 1ST FLOOR,PRINCE PLAZA SHOPPING COMPLEX CENTRE,GIDC AREA, ANKLESHWAR, BHARUCH, ANKLESWAR

**Manufacturing At** : KAMLA LIFESCIENCES LTD PLOT NO G-84/1
TARAPUR MIDC BOISAR PALGHAR 401506
MAHARASHTRA STATE, INDIA

**Drug License No** : 103908A In Form 28A

| Sr.No. | Name of the Product | Composition |
|---|---|---|
| 1 | REMWIN<br>REMDESIVIR FOR INJECTION 100 MG (LYOPHILIZED) | Each Vial Contains:<br>Remdesivir 100 mg<br>Excipients qs<br>Powder for concentrate for solution for infusion |

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