Serial No. 7537/20
Dated 11 JAN 2020

OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMIN MADHYA PRADESH

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. : 11 **Valid upto 27.08.2022**

On the basis of the inspection carried out on 25/06/2019 & 26/06/2019 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 & Address of site: **M/s Alpa Laboratories Limited**
33/2 A.B. Road Pigdamber 453 446
Indore Madhya Pradesh

2. Manufacturer's license No. **25/2/99 in Form No. 25**
28/2/99 in Form No. 28

3. Table: 1

Dosage Form(s)	Category (ies)	Activity(ies)
Dry Injection	General	Production , Packing , Labeling, Quality Control
Liquid Injection	General	Production , Packing , Labeling, Quality Control
Tablet	General	Production , Packing , Labeling, Quality Control
Capsule	General	Production , Packing , Labeling, Quality Control
Eye/Ear Drops & Ointment, Cream	General	Production , Packing , Labeling, Quality Control

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

4. This certificate remains valid until **27.08.2022** 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:

Office of the Controller
Food & Drugs Administration
Idgah Hills Bhopal (Madhya Pradesh)
Telephone No.: 0755-2666058
Fax No. : 0755-2665385

Name of authorized person:

Signature

Stamp and date:

Licensing Authority,
Food & Drugs Administration
Idgah Hills
Bhopal (Madhya Pradesh)

Shobhit Koshta
Licensing Authority
Food & Drugs Adminstration
Madhya Pradesh

Digitally signed by Sîli Oleg
Date: 2022.01.05 09:35:54 EET
Reason: MoldSign Signature
Location: Moldova

ATTESTED
MOHAN PAL
NOTARY DISTT. INDORE
M.P. GOVT.

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 license for the site, this number should be specified Record "not applicable" in cases where is not legal framework for the issuing of a licence.

(4) Table 1
List the dosage forms, staring materials, categories and activates. Examples are given below.

Example 1

Pharmaceutical Products(S)[2]	Category (ies)	Activity(ies)
Dosage form (s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production , Packaging , Quality Control
	Penicillin	Repackaging and labeling
	Cefalosporin	Aseptic preparation packaging, labeling

Example 2

Pharmaceutical Products(S)[2]	Category (ies)	Activity(ies)
Starting material (s)[3]		
Paracetamol	Analgesic	Synthesis, purification packing, labeling

Use, whenever available, International Nonproprietary Name (INNs) or otherwise national non proprietary name.

(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 in the manufacture and quality control of drugs refereed to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related material. Good Manufacturing Practices and Inspection, Volume 2, 1999 World Health Organization, Geneva and Subsequent updates.

Serial No. 758/20
Date 11 JAN 2020

NOTARIAL NOTARIAL

FORM-26
(See Rule 73 & 83)

CERTIFICATE OF RENEWAL OF LICENSE TO MANUFACTURER FOR SALE OF DRUGS OTHER THAN THOSE SPECIFIED IN THE SCHEDULE X

1. Certified that License No. 28/2/99 granted on the 18.03.1999 to Directors of **M/s Alpa Laboratories Limited,** for the Manufacturer of the following categories of drugs being drugs other than those specified in Schedules C and C (1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules,1945, at the premises situated at **33/2 A.B. Road Pigdamber 453 446 Indore MP India has been renewed from 01.01.2013 to 31.12.2017**

2. Name (s) of approved Competent Technical Staff :-

On Manufacturing Side	**Mr. Pradeep Soni**	**MC-517**
	Mr. Ashutosh Dubey	**MC-828**
	Mr. Vishnu Mohariya	**MC-1389**
On testing side:-	**Ms. Geeta Verma**	**ANACHEM-389**

M/s Alpa Analytical Laboratories
33/2 A.B. Road Pigdamber Indore MP

3. Name of the Drugs **As per list enclosed (Total 673 items Only)**

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P. BHOPAL

Date:- 17 OCT 2014

- Before manufacturing drugs containing sex Hormones corticosterio Beta Lactum antibiotics (Penicillin Group) and Antineoplastic Drugs the Licensee shall provided adequate arrangements to prevent their cross contamination with other drugs and obtain clearance from the Administration.

- The Licensee shall not manufacturer any drug formulation which is prohibited by Govt. of India U/S 26-A of the Drugs and cosmetics Act, 1940 from time to time.

NOTARY MOHAN PAL Notary Distt. Indore M.P. Govt. M.P. GOVT.

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH
17 OCT 2014

ATTESTED

MOHAN PAL
NOTARY DISTT. INDORE
M.P. GOVT.

OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
(MADHYA PRADESH)

No. V/28/I.C./A- 714 /2019/ 717 Indore Camp Dated: 15-10-2019

Serial No. 259/20
19 JAN 2020

TO WHOM SO EVER IT MAY CONCERN

M/s Alpa Laboratories Ltd. ,33/2 A.B. Road Pigdamber 453 446 Indore Mad holding Drugs Manufacturing License No. 25/2/99 in Form 25 & 28/2/99 in Form 28 Valid upto 31.12.2017.. The license has deposited requisite online fee for retention of license (s) as per this office record vide application No.INDB1625R33 and INDB1628R43.

In view of above as per GSR 1337 (E) dated 27.10.2017 the above mention license is deemed to be valid for a period of 5 years i.e. upto 31.12.2022.

To,
M/s Alpa Laboratories Ltd.
33/2 A.B. Road Pigdamber 453 446
Indore Madhya Pradesh

15/10/19
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

NOTARY MOHAN PAL Indore (M.P.) GOVT.

ATTESTED
MOHAN PAL
NOTARY, DISTT. INDORE
M.P. GOVT.