EP-4

OFFICE OF THE CONTROLLER: FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

No. V/WHO-GMP/ 6154 Bhopal, date :

To,

[redacted]

NOTARY GOVT. OF INDIA

ASHOK M. PANDYA Notary Govt. of India

Subject:- Revalidation of Certificate of Pharmaceutical Products.

Please find enclosed herewith the Certificate of Pharmaceuticals Products under WHO-GMP Certification Scheme under Certificate Valid up to [illegible] in respect of Pharmaceuticals Products (A.P.I) granted as per list enclosed under licence no. 3 in Form 25 & 28 as per recommendation by the office of the Dy. Drugs Controller (I) CDSCO, West Zone, Mumbai's vide Letter No 69/COPP/MP/WZ-2013/2932 Dated 13 – 06 – 2013

Encl:- Total Certificate :- One Page
List of Countries:- One Page
List of Items :- 3 page (70 Products)

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Licensing Authority
Food & Drugs Administration
Madhya Pradesh

LICENSING AUTHORITY
FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

No. V/WHO-GMP/

CC to:

1. The Dy.Drugs Controller(India), CDSCO, West Zone, 4th Floor, Central FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai, Central Mumbai-400 008 with reference to your referred letter please.
2. The Drugs Inspector, C/o Dy. Director, Food & Drugs Administration, Indore for Information.

THE ALL INDIA EXPORTERS' CHAMBER MUMBAI-INDIA

LICENSING AUTHORITY
FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

OFFICE OF THE CONTROLLER: FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

Certificate No. :
Valid up to –

Exporting Country: India
Importing Country: please refer Annexure – I

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This Certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

1.	Name (if applicable) & dosage form Product	:	As per enclosed list
1.1.	Is this product licensed to be placed on the market for use in the exporting country?	:	Yes
1.2.	Is this product actually on the market in the exporting country?	:	Yes

If the answer to 1.2 is yes, continue with section 2A. If the answer to 1.2 is no, omit section 2A, and continue with section 2B.

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2A

2A1	Number of product license & date of issue:	
2A2	Product license holder (name & address):	
2A3	Status of license holder a/b/c (key in appropriate category as defined in note B):	Manufacture the dosage form.
	For categories b & c the name & address of the manufacture producing the dosage from are:	Not Applicable
2A4	Is summary basis of approval appended?	Yes ☐ No ☑
2A5	Is the attached officially approved product information complete and consonant with the license?	Yes ☐ No ☐ Not Provided ☑
2A6	Applicant for certificate if different from the license holder (name & address):	Not Applicable

2B

2B1	Applicant for certificate (name & address)	Not Applicable
2B2	Status of Applicant:	Not Applicable
	For categories b & c the name & address of the manufactures	Not Applicable
2B3	Why is marketing authorization lacking:	Not Applicable
2B4	Remarks	Not Applicable

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3.	Does the certificate authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? If no nor not applicable proceed to question 4.	:	Yes ☑	No ☐ Not applicable ☐
3.1.	Periodicity of routine inspections (Years):	:	Once in a Year	
3.2.	Has the manufacture of this type of dosage form been inspected?	:	Yes ☑	No ☐ Not applicable ☐
3.3.	Do the facilities & operations conform to GMP as recommended by the World Health Organization?	:	Yes ☑	No ☐ Not applicable ☐
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspect of the manufacture of the product undertaken by another party?	:	Yes ☐	No ☐ Not applicable ☑

Name of certifying authority: : Office of the Controller, Food & Drugs Administrations, Madhya Pradesh, Bhopal, India

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Name of the authorized person:

Signature

Licensing Authority
Food & Drugs Adminstration
Madhya Pradesh

Licensing Authority
Food & Drugs Administration
Bhopal (M.P.)

Stamp & Date
Telephone No. : 0091 – [illegible]
Fax No : 0091 – [illegible] 2665385

THE ALL INDIA EXPORTERS' CHAMBER MUMBAI-INDIA

ASHOK M. PANDYA
Notary
Govt. of
India

LIST OF COUNTRIES

Sr. No	Name of Countries	Sr. No.	Name of Countries	Sr.No.	Name of Countries
01.	ALGERIA	56	IRAN	111	PORTUGAL
02.	AUSTRALIA	57	IRAQ	112	POLAND
03.	ARMENIA	58	IVORY COAST	113	PUERTO RICO
04.	AUSTRIA	59	INDONESIA	114	QATAR
05.	ARGENTINA	60	IRELAND	115	ROMANIA
06.	AZERBAIJAN	61	ITALY	116	RUSSIA
07.	ANGOLA	62	JORDAN	117	RWANDA
08.	BAHRAIN	63	JAMAICA	118	SRILANKA
09.	BELARUS	64	JAPAN	119	SENEGAL
10	BENIN	65	KAZAKHSTAN	120	SOUTH AFRICA
11.	BURKINA FASO	66	KENYA	121	SUDAN
12.	BELGIUM	67	KHYRGHYZSTAN	122	SINGAPORE
13.	BRAZIL	68	KUWAIT	123	SAUDI ARABIA
14.	BAHAMAS	69	KOREA	124	SEYCHELLES
15	BANGLADESH	70	LEICHESTEIN	125	SIERRALEONE
16	BARBADOS	71	LEBANON	126	SOLVENIA
17	BOLIVIA	72	LATVIA	127	SOLOMON ISLANDS
18	BULGARIA	73	LITHUANIA	128	SOMALI
19	BOTSWANA	74	LESOTHO	129	SOMALIA
20	CAMEROON	75	LIBERIA	130	SOUTH KOREA
21	CZECH REPUBLIC	76	LIBYA	131	SPAIN
22	CAMBODIA	77	LUXEMBOURG	132	SURINAM
23	CHINA	78	LAOS	133	SWAZILAND
24	COLUMBIA	79	MUSCAT	134	SWEDEN
25	COSTARICA	80	MALAWI	135	SYRIA
26	CIS	81	MAURITIUS	136	SLOVAK REPUBLIC
27	CONGO	82	MOLDOVIA	137	SWITZERLAND
28	CHILE	83	MOROCCO	138	TANZANIA
29	CANADA	84	MEXICO	139	TOGO
30	CUBA	85	MALAYSIA	140	THAILAND
31	CYPRUS	86	MYANMAR	141	TRINIDAD & TOBAGO
32	DOMINICAN REPUBLIC	87	MAURITANIA	142	TUNISEA
33	DENMARK	88	MADAGASKAR	143	TAIWAN
34	EGYPT	89	MALDIVES	144	TURKEY
35	ESTONIA	90	MALI	145	UAE
36	ETHIOPIA	91	MALTA	146	UGANDA
37	EL – SALVADOR	92	MOZAMBIQUE	147	UNITED KINGDOM
38	FINLAND	93	MONACO	148	UKRAINE
39	FIJI	94	MONGOLIA	149	UZBEKISTAN
40	FRANCE	95	MACAU	150	U.S.A.
41	FRENCH GUIANA	96	NEPAL	151	URUGUAY
42	GABON	97	NIGERIA	152	VENEZUELA
43	GHANA	98	NICARAGUA	153	VIETNAM
44	GUATEMALA	99	NORWAY	154	VIRGIN ISLAND
45	GEORGIA	100	NETHERLANDS	155	YEMEN
46	GERMANY	101	NAMIBIA	156	YOGOSLAVIA
47	GUYANA	102	NEW ZEALANDS	157	ZAIRE
48	GREECE	103	NIGER	158	ZAMBIA
49	GUINEA	104	OMAN	159	ZIMBABWE
50	HUNGARY	105	PHILIPPINES		
51	HONGKONG	106	PANAMA		
52	HONDURAS	107	PERU		
53	HAITI	108	PAKISTAN		
54	HAWAI	109	PAPUA NEW GUINEA		
55	ICELAND	110	PARAGUAY		

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M.P. BHOPAL

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MUMBAI-INDIA

Licensing Authority
Food & Drugs Adminstration
Madhya Pradesh

Licensing Authority
Food & Drugs Administration
Bhopal (M.P.)

Certificate
Valid up to

Following Items (APIs) covered under WHO-GMP

Sr. No.	Product
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 Madhya Pradesh

Bhopal M.P.

Welfare

Services

Valid up to

LIST OF PRODUCTS FOR CERTIFICATE : WHO – GMP

Sr. No.	Product
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Food & Drugs Administration
Bhopal (M.P.)

Licensing Authority
Food & Drugs Administration
Madhya Pradesh

THE ALL INDIA EXPORTERS' CHAMBER
MUMBAI-INDIA

Certificat
Valid

LIST OF PRODUCTS FOR – WHO – GMP CERTIFICATE

Sr. No.	Product
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CONTROLLER FOOD & DRUGS ADMINISTRATION M.P. BHOPAL

Ipca Laboratories Limited Ratlam QUALITY ASSURANCE

TRUE-C(

Drugs Inspector
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
CDSCO West Zone Mumbai

Licensing Authority
Food & Drugs Administration
Bhopal (M.P.)

Licensing Authority
Food & Drugs Adminstration
Madhya Pradesh

ASHOK M. PANDYA Notary Govt. of India

ATTESTED BY ME

Advocate & Notary (Govt Of India)
C-6, Diamond Apt., Behind Diamond-Cinema, L. T. Road, Borivali (W), MUMBAI - 400 092.