



Office of the Controller, Food and Drugs Administration

Madhya Pradesh, Idgah Hills, Bhopal (M.P.)-462001

Tel.: 0755-2665385, E-mail : cf damp@rediffmail.com, fdampbhopal@gmail.com

No. V/WHO-GMP/ Rev I-5/2022 / 2830

BHOPAL, Dated 13-05-2022

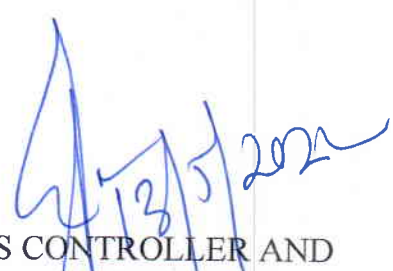
To,

M/s Ipca Laboratories Limited
P.O. Sejavta
District Ratlam (M.P)
457001
INDIA

Sub: Revalidation of Certificate of Pharmaceutical Product.

Please find enclosed herewith the Certificate of Pharmaceutical Product under WHO-GMP Certification Scheme under Certificate No. 04/2006 Valid up to 12.05.2025, in respect of Pharmaceuticals Product (API) granted as per list enclosed under license no. 25/35/83 and 25F/35/83 in Form 25 as per recommendation by the office of Deputy Drugs Controller (I), CDSCO Bhawan, GPO Square, Residency Area, A.B. Road, Indore (M.P.) Vide Letter No.SZI/2019/COPP/IPCA Ratlam/ 012/198 dated 28.04.2022.

Encl: Total Certificate: - One Page
List of Countries: - One page
List of Items: - As per Annexure I


DY.DRUGS CONTROLLER AND
LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

Endt. No.V/WHOGMP/Rev I-5/2022 /

BHOPAL, Dated

CC to:

- 1) The Drug Inspector, C/o Dy. Director, Food and Drugs Administration, Ratlam for information.


DY.DRUGS CONTROLLER AND
LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

**OFFICE OF THE CONTROLLER FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH**

Certificate No: 04/2006

Valid up to: - 12.05.2025

Exporting Country: India

Importing County: Please refer Annexure II

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conform to the format recommended by World Health Organization

(General instruction and explanatory notes attached)

1. Name (if applicable) & dosage form of product

: As Per enclosed list –Annexure I

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

2A		2B	
2A1	Number of product license & date of issue:	2B1	Applicable for certificate (Name & Address) : Not Applicable
	: 25/35/83 & 25F/35/83 dated 03/01/1989		
2A2	Product & license holder	2B2	Status of Applicant : Not Applicable
	: M/s Ipca Laboratories Limited, P.O. Sejavta District - Ratlam (M.P) India Pin- 457001		For categories b & c the name & address of the manufactures : Not Applicable
2A3	Status of license holder a/b/c (key in appropriate category as defined in note B):	2B3	Why is marketing authorization lacking? : Not Applicable
	: Manufacture the API		
	For categories b & c the name & address of the manufacturer producing the dosage from are:	2B4	Remarks : Not Applicable
	: 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 license holder (name & address) : Not Applicable		

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is product? If no or not applicable proceed to question 4.

: Yes ☒ No ☐ Not Applicable ☐

3.1 Periodicity of routing inspection (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 confirm to GMP as recommended by the Word Health Organization?

: Yes ☒ No ☐ Not Applicable ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of product undertaken by another party?

: Yes ☐ No ☐ Not Applicable ☒

Name of certifying authority

Name of authorized person

Signature

Stamp and Date

Telephone No. : 0091-755-2666058

Fax No. : 0091-755-2665385

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Dy. Drugs Controller
State Licensing Authority
Food & Drugs Administration
Madhya Pradesh

Office of the Controller
Food and Drugs Administration
Bhopal Madhya Pradesh India

Annexure - I

M/s Ipca Laboratories Limited, P.O. Sejavta, Dist.-Ratlam-457001, (M.P.) INDIA
LIST OF EXISTING PRODUCTS FOR RENEWAL OF COPP
[Active Pharmaceutical Ingredients]

Certificate No.04/2006

Valid Up to. 12.05.2025

Sr. No.	Name of Products
1.	α - β Arteether IP
2.	Allopurinol IP/BP/EP/USP
3.	Amlodipine Besylate IP/BP/EP/USP
4.	Amodiaquine Hydrochloride IP/USP/FP
5.	Amyl Meta Cresol BP/EP
6.	Artemether INP/IP
7.	Artesunate INP/IP
8.	Artesunate [Sterile]
9.	Atenolol IP/BP/EP/USP/JP/CP
10.	Atovaquone
11.	Bendroflumethiazide BP/EP/USP
12.	Bisoprolol Fumarate USP/BP/EP
13.	Carvedilol BP/EP/IP/USP
14.	Cetirizine Di Hydrochloride IP/BP/EP/USP
15.	Chloroquine Phosphate IP/BP/EP/USP
16.	Chlorthalidone IP/BP/EP/USP
17.	Cilostazol JP/USP/IP
18.	Citalopram Hydrobromide IP/BP/EP/USP
19.	Clopidogrel Bisulphate USP/IP
20.	Clopidogrel Hydrogen Sulfate EP
21.	Dihydroartemisinin IHT/Int.Ph.
22.	2-4 Dichloro Benzyl Alcohol
23.	Ebastine IP/BP/EP
24.	Etodolac BP/EP/USP/IP
25.	Etodolac Sodium
26.	Eszopiclone USP
27.	Famotidine IP/BP/EP/USP/JP



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State Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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Annexure - I

M/s Ipca Laboratories Limited, P.O. Sejavta, Dist.-Ratlam-457001, (M.P.) INDIA
LIST OF EXISTING PRODUCTS FOR RENEWAL OF COPP
[Active Pharmaceutical Ingredients]

Certificate No.04/2006

Valid Up to. 12.05.2025

Sr. No.	Name of Products
28.	Fenofibrate BP/EP/USP/IP
29.	Fluconazole EP/USP/BP/CP
30.	Flumequine BP/EP
31.	Furosemide IP/BP/EP/USP/JP
32.	Glimepiride BP/EP/USP/IP/JP
33.	Hydrochlorothiazide IP/BP/EP/USP/JP
34.	Hydroxy Chloroquine Sulphate BP/EP/USP/IP
35.	Hydroxyzine DI HCL BP/EP/USP
36.	Indapamide BP/EP/USP/CP/IP
37.	Losartan Potassium USP/IP/EP/BP
38.	Lumefantrine Ph.Int.
39.	Levofloxacin Hemihydrate IP
40.	Levofloxacin USP
41.	Levofloxacin Hydrate JP
42.	Lamotrigine USP/Ph.Eur.
43.	Mesalamine / Mesalazine BP/EP/USP/IP
44.	Metformin Hydrochloride IP/BP/EP/USP/CP/JP
45.	Methylphenidate Hydrochloride USP/EP/BP
46.	Metoclopramide Base BP/EP/JP
47.	Metoclopramide Hydrochloride IP/BP/EP/USP
48.	Metoprolol Succinate BP/EP/USP
49.	Metoprolol Tartrate IP/BP/EP/USP/JP
50.	Midodrine Hydrochloride USP
51.	Morantel Citrate IHT
52.	Nabumetone BP/EP/USP
53.	Nifedipine EP/USP
54.	Ondansetron Hydrochloride ^{Dihydrate} BP/EP/USP/IP & Ondansetron Hydrochloride IP



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Dy. Drugs Controller
State Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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Annexure - I

M/s Ipca Laboratories Limited, P.O. Sejavta, Dist.-Ratlam-457001, (M.P.) INDIA

LIST OF EXISTING PRODUCTS FOR RENEWAL OF COPP
[Active Pharmaceutical Ingredients]

Certificate No.04/2006

Valid Up to. 12.05.2025

Sr. No.	Name of Products
55.	Ondansetron USP/IP
56.	Paroxetine HCL Hemihydrate BP/EP/USP
57.	Primaquine Phosphate IP/BP/EP/USP
58.	Probenecid IP/BP/EP/USP
59.	Proguanil HCL IP/BP/EP/USP
60.	Propranolol HCL IP/BP/EP/USP/JP
61.	Promethazine HCL IP/BP/EP/USP
62.	Pyrantel Pamoate / Embonate EP/USP/JP/IP
63.	Pyrimethamine IP/BP/EP/USP
64.	Quetiapine Hemifumarate IHT
65.	Quetiapine Fumarate IP/EP/USP
66.	Risedronate Sodium USP
67.	Risperidone EP/BP/USP
68.	Ractopamine Hydrochloride IHT
69.	Sodium Alendronate BP/EP/USP
70.	Sulphadoxine IP/BP/EP/USP
71.	Torsemide BP/EP/USP
72.	Tramadol HCL IP/BP/EP/USP
73.	Triclabendazole IHT/Ph.Eur.
74.	Trimethoprim IP/BP/EP/USP/JPC
75.	Triameterene IP/BP/EP/USP
76.	Telmisartan IP/BP/EP/USP
77.	Valsartan IP/BP/EP/USP
78.	Venlafaxine Hydrochloride USP/Ph.Eur.
79.	Warfarin Sodium Clathrate BP/EP/USP
80.	Warfarin Sodium IP/EP/USP
81.	Zolendronic Acid IP/IHT
82.	Zopiclone Ph.Eur.



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State Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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ANNEXURE-II

IPCA LABORATOIRES LIMITED, P.O.- SEJAVTA, RATLAM (M.P.) 457001- INDIA

Certificate No. 04/2006

Valid Up to 12.05.2025

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	LEICHESTEN	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	MALEDIVES	144	TURKEY
35	ESTONIA	90	MAEI	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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