AZ 5247 KF

Chile

AstraZeneca UK Limited
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom
T: +44 (0) 20 3749 5000

astrazeneca.com

TO WHOM IT MAY CONCERN

Good Manufacturing Practice Certificate

t is hereby confirmed that the attached Certificate is a true copy of the original document.

Signature Attested by Phillip Jones
Solicitor and Notary
Windsor House, Victoria Street,
Windsor, Berks, SL4 IEN, England,
Tel: 01753 851591

2/1/18

Signed: ..... Dated 21/12/17

Vicky Beattie
Regulatory Project Assistant
Regulatory Project Management Group
AstraZeneca UK Limited

AstraZeneca UK Limited is a subsidiary of AstraZeneca PLC
Registered in England No. 3674842
Registered office: 1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom

6/18

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	Phillip H Jones
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public

Certified

Attesté / Certificado

5. at á / en	London	**6. the** le / el día	04 January 2018
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs		
8. Number sous no / bajo el numero	APO-678888		
9. Seal / stamp Sceau / timbre Sello / timbre	FOREIGN AND COMMONWEALTH OFFICE LONDON	**10. Signature** Signature Firma	M. Gaffey MG

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OFFICE OF THE CONTROLLER: FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

No. V/WHO-GMP/ I-6/2017/ 4512 **Bhopal, dated** 14/09/2017

To,
M/s Ipca Laboratories Limited
P.O. Sejavta
District – Ratlam.
(M.P.)
India

Subject:- Revalidation of Certificate of Pharmaceutical Products.

Please find enclosed herewith the Certificate of Pharmaceuticals Products under WHO-GMP Certification Scheme under Certificate No. 04/2006, Valid up to ...13.SEP.2019.. in respect of Pharmaceuticals Products (A.P.I) granted as per list enclosed under license no. 25/35/83 & 28/20/83 in Form 25 & 28 as per recommendation by the office of the Dy.D.C. (I) CDSCO, Sub Zone, Indore vide Letter No. SZI/2017/COPP/API/IPCA/018 Dated 12.09.2017.

14.9.17

DY. DRUG CONTTOLLER &
LICENSING AUTHORITY
FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

No. V/WHO-GMP/ I-6/2017/ **Bhopal, dated**

CC to:

Copy forwarded to:-
1. **The Dy. Drugs Controller (India), CDSCO, Sub- Zonal, 67-72, Type –I , Griffins Colony Piplyahana Road , M.Y. Road Hospital Main Road Indore M.P. for information.**
2. **The Drugs Inspector C/o Dy Director , Food and Drugs Administration Ratlam for Information.**

sd

DY. DRUG CONTTOLLER &
LICENSING AUTHORITY
FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

OFFICE OF THE CONTROLLER FOOD & DRUGS ADMINISTRAION
MADHYA PRADESH

Certificate No: 04/2006
Valid up to: - 13 SEP 2013

Exporting Country: India
Importing County: Please refer Annexure III

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 Annexure I and II**

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:	: 25/35/83 & 28/20/83 dated 03/01/1989	2B1 Applicable for certificate (Name & Address)	: Not Applicable
2A2 Product & license holder (Name & Address):	: M/s IPCA LABORATORIES LIMITED, P.O Sejavta District Ratlam (M.P) India Pin- 457002	2B2 Status of Applicant	: Not Applicable
		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):	: Manufacture the API	2B3 Why is marketing authorization lacking?	: Not Applicable
For categories b & c the name & address of the manufacturer producing the dosage from are:	: Not Applicable	2B4 Remarks	: 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		

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage from 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 from 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

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

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

Ipca Laboratories Limited,
Ratlam (M.P.), INDIA

ipca

Annexure-I

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

Certificate No. 04/2006
Valid up to...13-SEP-2019

Sr. No.	Product
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
10.	Bendroflumethiazide BP/EP/USP
11.	Bisoprolol Fumarate USP/BP/EP
12.	Carvedilol BP/EP/IP/USP
13.	Cetirizine Di Hydrochloride IP/BP/EP
14.	Chloroquine Phosphate IP/BP/EP/USP
15.	Chlorthalidone IP/BP/EP/USP
16.	Cilostazol JP/USP
17.	Citalopram Hydrobromide IP/BP/EP/USP
18.	Clopidogrel Bisulphate USP
19.	Clopidogrel Hydrogen Sulfate EP
20.	Dihydroartemisinin IHT/INP.
21.	2,4- Dichlorobenzyl Alcohol
22.	Ebastine IP/BP/EP
23.	Etodolac BP/EP/USP/IP
24.	Fenofibrate BP/EP/USP/IP
25.	Fluconazole EP/USP/BP/CP

FOOD & DRUGS ADMINISTRATION CONTROLLER M.P. BHOPAL

Ipca Laboratories Limited. Ratlam QUALITY ASSURANCE 07/09/19

07/9/19
Basant Kumar Yadav
Drugs Inspector
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
O/o. Assistant Drugs Controller (India)
CDSCO Sub-Zone,INDORE

14-9-19
SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

Ipca Laboratories Limited,
Ratlam (M.P.), INDIA

ipca

Annexure-I

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

Certificate No. 04/2006
Valid up to....13-SEP-2012

Sr. No.	Product
26.	Flumequine BP/EP
27.	Furosemide IP/BP/EP/USP/JP
28.	Glimepiride BP/EP/USP/IP
29.	Hydrochlorothiazide IP/BP/EP/USP/JP
30.	Hydroxy Chloroquine Sulphate BP/EP/USP
31.	Hydroxyzine DI HCl BP/EP/USP
32.	Indapamide BP/EP/USP/CP
33.	Losartan Potassium USP/IP/EP/BP
34.	Lumefantrine Ph. Int.
35.	Mesalamine BP/EP/USP
36.	Metformin Hydrochloride IP/BP/EP/USP/CP/JP
37.	Methylphenidate Hydrochloride USP/EP/BP
38.	Metoclopramide Base BP/EP/JP
39.	Metoclopramide Hydrochloride IP/BP/EP/USP
40.	Metoprolol Succinate BP/EP/USP
41.	Metoprolol Tartrate IP/BP/EP/USP/JP
42.	Midodrine Hydrochloride USP
43.	Morantel Citrate IHT
44.	Nabumetone BP/EP/USP
45.	Nifedipine EP/USP
46.	Ondansetron Hydrochloride BP/EP/USP/IP
47.	Ondansetron USP / IP
48.	Paroxetine HCl Hemihydrate BP/EP/USP
49.	Primaquine Phosphate IP/BP/EP/USP
50.	Probenecid IP/BP/EP/USP

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

Ipca Laboratories Limited, Ratlam
QUALITY ASSURANCE
07/09/12

Basant Kumar Yadav
Drugs Inspector
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
O/o. Assistant Drugs Controller (India)
CDSCO Sub-Zone, INDORE

14-9-12

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

Ipca Laboratories Limited,
Ratlam (M.P.), INDIA

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Annexure-I

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

Certificate No. 04/2006
Valid up to.....13 SEP 2013

Sr. No.	Product
51.	Proguanil Hcl IP/BP/EP
52.	Propranolol HCl IP/BP/EP/USP/JP
53.	Promethazine Hcl IP/BP/EP/USP
54.	Pyrantel Pamoate / Embonate EP/USP/JP/IP
55.	Pyrimethamine IP/BP/EP/USP
56.	Quetiapine Hemifumarate IP/IHT
57.	Risedronate Sodium USP
58.	Risperidone EP/BP/USP
59.	Ractopamine Hydrochloride IHT
60.	Sodium Alendronate BP/EP/USP
61.	Sulphadoxine IP/BP/EP/USP
62.	Torsemide BP/EP/USP
63.	Tramadol HCl IP/BP/EP/USP
64.	Triclabendazole IHT
65.	Trimethoprim IP/BP/EP/USP/JPC
66.	Triameterene IP/BP/EP/USP
67.	Telmisartan IP/BP/EP
68.	Valsartan IP/BP/EP/USP
69.	Warfarin Sodium Clathrate BP/EP/USP
70.	Warfarin Sodium IP/EP/USP
71.	Zolendronic Acid IP/IHT

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

03/09/12

Basant Kumar Yadav
Drugs Inspector
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
O/o. Assistant Drugs Controller (India)
CDSCO Sub-Zone,INDORE

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

Ipca Laboratories Limited, Ratlam
QUALITY ASSURANCE

Ipca Laboratories Limited,
Ratlam (M.P.), INDIA

ipca

Annexure-II

LIST OF PRODUCTS FOR WHICH WHO – GMP CERTIFICATE IS REQUIRED

Certificate No. 04/2006
Valid up to.....13 SEP 2013

Sr. No.	Product
1.	Atovaquone
2.	Cetirizine Di Hydrochloride USP
3.	Cilostazol IP
4.	Clopidogrel Bisulphate IP
5.	Etodolac Sodium
6.	Famotidine IP/BP/EP/USP/JP
7.	Glimepiride JP
8.	Hydroxy Chloroquine Sulphate IP
9.	Indapamide IP
10.	Lamotrigine IP/BP/USP/Ph.Eur.
11.	Mesalazine IP
12.	Triclabendazole Ph.Eur.
13.	Venlafaxine Hydrochloride USP/Ph.Eur.

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

Ipca Laboratories Limited, Ratlam
QUALITY ASSURANCE

08/09/12

Basant Kumar Yadav
Drugs Inspector
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
O/o. Assistant Drugs Controller (India)
CDSCO Sub-Zone,INDORE

14.9.12

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

ANNEXURE-III

Certificate No. 04/2006
Valid Up to 13 SEP 2019

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

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		

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

14.9.19

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh