File No. AYUSH/Charak-Baddi/06/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(AYUSH Section)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:
31 JAN 2020

To,

M/s. Charak Pharma Pvt. Ltd.
Village Katha, P.O. Baddi,
Teh. Nalagarh, Distt. Solan, H. P. 173205

Subject: Revalidation of WHO-GMP Certificate and Certificate of Pharmaceutical Product (CoPP) of 11 Ayurvedic drugs and 01 additional drug as per WHO certification scheme – reg.

Sir,

With reference to your application on the subject matter, please find herewith the WHO-GMP Certificate vide no. WHO-GMP/CHARAK-BADDI/01/2020 dated 30-01-2020 and Certificate of Pharmaceutical Product (CoPP) of the following 11 Ayurvedic drugs and 01 additional drug as per WHO certification scheme:

1. Extrammune Tablets
2. Fortyfitt Tablets
3. Galakol Tablets
4. Haleezy Tablets
5. Obenyl Tablets
6. Pilief Tablets
7. Regulax Forte Tablets
8. Sumenta Tablets
9. Vigomax Forte Tablets
10. Stop IBS Tablets
11. Zzowin Tablets
12. Kofol Chewable Tablets

Please acknowledge the receipt.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (I)

Copy to: 1. Dr. D.C. Katoch, Advisor (Ay.), AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi 110023.

2. Sh. Sanjeev Bhatnagar, Director cum Licensing Authority, B-26, Ayurved Bhawan, SDA complex, Kasumpti, Shimla, H.P- 171009.

GOVERNMENT OF INDIA
Directorate General of Health Services
Ministry of Health & Family Welfare
Central Drugs Standard Control Organization

Certificate of Good Manufacturing Practices

(This one –page certificate conforms to the format recommended by the World Health Organization (general instructions and Explanatory notes attached).[1]

Certificate No: - WHO-GMP/CHARAK-BADDI/01/2020

On the basis of the inspection carried out on **21/11/2019-22/11/2019** 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 and Address of Site:** M/s. Charak Pharma Pvt.Ltd.
Village Katha, P.O. Baddi,
Teh. Nalagarh, Distt. Solan, H. P. 173205
2. **Manufacturer's Licence Number:** HP-128-Ay

3. Table : 1

Dosage Form (S)	Category (ies)	Activity (ies)
Tablets	Menstrual Modulator, Antioxidant & Immunity booster, Digestive aid, Relieves Cough ,Hepatoprotector, Appetite Stimulant, Anti–nauseant, anti-emetic, Bronchodilator, Anti-Inflammatory, Anti-allergic, Carminative, Carminative, Cognitive insufficiency, Anti-histaminic, to treat Menorrhagia, Immunity Enhancer, Urine alkaliser	Production ,Quality Control,Labelling & Packing

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 30 JAN 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:
Central Drugs Standard Control Organization,
FDA Bhavan, ITO, Kotla Road ,
New Delhi- 110 002

Name and Function of responsible person:
Dr. V. G. Somani
Drugs Controller General (I)
Email : dci@nic.in
Telephone No:- 91 11 23236965
Fax No: - 91 11 23236973

Signature:

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp & Date:

31 JAN 2020

Appendix-I

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, FDA BHAVAN, ITO, KOTLA ROAD, NEW DELHI - 110002

Appendix to following Certificate Nos. of

M/s Charak Pharma Pvt. Limited
Village Katha, P.O.Baddi,
Teh. Nalagarh, Distt. Solan, H.P. 173205.

Valid Up to: 30 JAN 2023

Under License No.: **HP-128-Ay**

For their Products:

Name of Product	COPP No.	Name of Product	COPP No.
Extrammune Tablets	WHO-GMP/CoPP/CHRK-Baddi/01/2020	Regulax Forte Tablets	WHO-GMP/CoPP/CHRK-Baddi/07/2020
Fortyfitt Tablets	WHO-GMP/CoPP/CHRK-Baddi/02/2020	Sumenta Tablets	WHO-GMP/CoPP/CHRK-Baddi/08/2020
Galakol Tablets	WHO-GMP/CoPP/CHRK-Baddi/03/2020	Vigomax Forte Tablets.	WHO-GMP/CoPP/CHRK-Baddi/09/2020
Haleezy Tablets	WHO-GMP/CoPP/CHRK-Baddi/04/2020	Stop IBS Tablets	WHO-GMP/CoPP/CHRK-Baddi/10/2020
Obenyl Tablets	WHO-GMP/CoPP/CHRK-Baddi/05/2020	Zzowin tablets	WHO-GMP/CoPP/CHRK-Baddi/11/2020
Pilief tablets	WHO-GMP/CoPP/CHRK-Baddi/06/2020	Kofol Chewable tablets	WHO-GMP/CoPP/CHRK-Baddi/12/2020

For the following countries:

Sr. No.	Name of country	Sr. No.	Name of country	Sr. No.	Name of country	Sr. No.	Name of country
1.	Algeria	41.	French Guiana	81.	Mauritius	121.	Singapore
2.	Australia	42.	Gabon	82.	Maldovia	122.	Saudi Arabia
3.	Armenia	43.	Ghana	83.	Morocco	123.	Seychelles
4.	Austria	44.	Guatemala	84.	Mexico	124.	Seiraleone
5.	Argentina	45.	Georgia	85.	Malaysia	125.	Slovenia
6.	Azerbahan	46.	Germany	86.	Myanmar	126.	Solomon Islands
7.	Bahrain	47.	Guyana	87.	Mauritania	127.	Somali
8.	Belarus	48.	Greece	88.	Madagaskar	128.	Somalia
9.	Benin	49.	Guinea	89.	Maldives	129.	South Korea
10.	Burkina Faso	50.	Hungary	90.	Mali	130.	Spain
11.	Belgium	51.	Hong Kong	91.	Malia	131.	Surinam
12.	Brazil	52.	Honduras	92.	Mozambique	132.	Swaziland
13.	Bahamas	53.	Haiti	93.	Monaco	133.	Sweden
14.	Bangladesh	54.	Hawai	94.	Mongolia	134.	Syria
15.	Barbados	55.	Iceland	95.	Nepal	135.	Slovak Republic
16.	Bhutan	56.	Iran	96.	Nigeria	136.	Switzerland
17.	Bolivia	57.	Iraq	97.	Nicaragua	137.	Tanzania
18.	Bulgaria	58.	Ivory Coast	98.	Norway	138.	Togo

19.	Botswana	59.	Indonesia	99.	Netherlands	139.	Thailand
20.	Cameroon	60.	Ireland	100.	Namibia	140.	Thailand
21.	Czech Republic	61.	Italy	101.	New zelands	141.	Tunisea
22.	Cambodia	62.	Jordan	102.	Niger	142.	Taiwan
23.	China	63.	Jamaica	103.	Oman	143.	Turkey
24.	Columbia	64.	Japan	104.	Philippines	144.	U.A.E.
25.	Costarica	65.	Kazakhstan	105.	Panama	145.	Uganda
26.	CIS	66.	Kenya	106.	Peru	146.	United Kingdom
27.	Congo	67.	Khyrohsztan	107.	Pakistan	147.	Ukraine
28.	Chile	68.	Kuwait	108.	Papua-New Guinea	148.	Uzbekistan
29.	Canada	69.	Korea	109.	Paraguay	149.	U.S.A.
30.	Cuba	70.	Leichestein	110.	Portugal	150.	Uruguay
31.	Cyprus	71.	Lebanon	111.	Poland	151.	Venezuela
32.	Dominican Republic	72.	Latvia	112.	Puerto Rico	152.	Vietnam
33.	Denmark	73.	Lithuania	113.	Qatar	153.	Virgin Island
34.	Egypt	74.	Lesotho	114.	Romania	154.	Yemen
35.	Estonia	75.	Liberia	115.	Russia	155.	Yugoslavia
36.	Ethiopia	76.	Libya	116.	Rwanda	156.	Zaire
37.	El-Salvador	77.	Luxembourg	117.	Sri Lanka	157.	Zambia
38.	Finland	78.	Laos	118.	Senegal	158.	Zimbabwe
39.	Fiji	79.	Muscat	119.	South Africa		
40.	France	80.	Malwai	120.	Sudan		

Address of certifying authority:
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
FDA BHAVAN, ITO, KOTLA ROAD,
NEW D ELHI – 110 002

Telephone No.: 011- 23236965
Tele / Fax: 011- 23236973 Stamp & Date

Name of authorized person:
(Dr. V. G. Somani)
Drugs Controller General (I)

Signature

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp and date

31 JAN 2020

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   a). manufactures the dosage form;
   b). packages and/or labels a dosage form manufactured by an independent company; or
   c). is involved in none of the above.
9. This information can only be provided with the consent of the product licence holder or, in the case of nonregistered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a). the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b). the product has been reformulated with a view to improving its stability under tropical conditions;
    c). the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d). the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e). any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.
17. The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.