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Reason: MoldSign Signature
Location: Moldova

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

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

Certificaste No.: No. HFW. H (Drugs) 217/09/2022/48 **VALID UPTO: 22/02/2025**

Exporting (certifying) country : **INDIA**
Importing (requesting) country : **Annexure Attached**
1. Name and dosage form of product : **Hydrocortisone Tablets USP**

1.1 Active ingredient (s) and Amount (s) per unit dose : Each uncoated tablet contains:
Hydrocortisone IP..... 20 mg

For complete qualitative composition including Excipients: N.A.

1.2 Is this product licensed to be placed on the market for use in the exporting country?

Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country?

Yes ☒ No ☐ Unknown ☐

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

2A .

A.1 No of product license And date of issue : MB/09/791 in Form No. 28 01.04.2020

A.2 Product License holder : M/s Samarth Life Sciences Pvt. Ltd. Unit-II Plot No. 2, Industrial Area, Vill. Lodhimajara, Baddi, Distt. Solan H.P. 173205 India

A.3 Status of Product-license Holder :
a ☒ b ☐ c ☐

A.3.1 For categories b and c, The name and address of the Manufacturer producing the dosage form are
Not Applicable

A.4 Is summary Basis of Approval appended ? :
Yes ☐ No ☒

A.5 Is the attached, officially approved product information Complete and consonant with the License ? :
Yes ☐ No ☐ Not provided ☒

A.6 Applicant for certificate if different from License holder :
Not Applicable

2B

B. 1 Applicant for certificate (name and address) :

B. 2 Status of applicant:
a ☐ b ☐ c ☐

B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are

B. 3 Why is marketing authorization lacking ?
Not Required ☐ Not Requested ☐ Under consideration ☐
Refused ☐

B. 4 Remark :

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

3.1 Periodicity of routine inspection (years) : Once in a year

3.2 Has the manufacture of this type of dosage form been inspected? : Yes

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization ? : Yes

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ? : Yes
If no ,explain:

Address of Certifying Authority:
State Drug Controller
Controlling Cum Licensing Authority
Baddi Distt. Solan (H.P) -173205
01795-244228, sdc4hp@gmail.com

Licensing Authority cum Drug Controller * Himachal Pradesh *

Name of the Authorized Person : Navneet Marwaha
Designation : State Drug Controller
Signature :
Stamp and Date :

NAVNEET MARWAHA
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H.P.) 173205
01795-244288,sdc4hp@gmail.com

08 MAR 2022

General Instructions

- Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme.
- The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand-written.
- Additional sheets should be appended as necessary, to accommodate remarks and explanations.

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 Non-proprietary Names (INNs) or National Non-proprietary 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 of the product license 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 license.
6) Sections 2A and 2B are mutually exclusive.
7) Indicate when applicable, if license is provisional, or the product has not yet been approved.
8) Specify whether the person responsible for placing the product on the market:
   a) Manufacturers the dosage forms:
   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 be provided only with the consent of the product - license holder or in the case of non-registered 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 license. If the production site is changed, the license must be updated or it will cease to be valid.
10) This refers to the document, prepared by some national regulatory authorities, that summaries 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 a Summary of Product Characteristics (SPC)
12) In this circumstance, permission of issuing the certificate is required from the product - license holder. The applicant must provide this permission to the authority.
13) Please indicate the reason that the applicant has provided for the 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 that the manufacture is taking 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 drug referred to in the certificate are those included in the thirty - second report of the Expert Committee on Specifications for Pharmaceuticals 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. 823, 1992, Annex 1).
16) This section is to be completed when the product - license 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.
    The layout for this Model certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.

Annexure to Certificate of a Pharmaceutical Product

Certificate No. HWF-H-(Drugs) 217/09/2022/48 Valid up to 22/02/2025 granted to
M/S SAMARTH LIFE SCIENCES PVT LTD. UNIT-II

For the following Countries:

1.	Albania	42.	Costa Rica	83	Iraq	124.	Nepal	165.	St. Kitts & Nevis
2.	Afghanistan	43.	Croatia	84	Ireland	125.	Netherlands Antilles	166.	St. Lucia
3.	Algeria	44.	Cuba	85	Italy	126.	New-Zealand	167.	St. Vincent
4.	Angola	45.	Cyprus	86	Ivory Coast	127.	Nicaragua	168.	Sudan
5.	Anguilla	46.	Czechoslovakia	87	Jamaica	128.	Niger	169.	Sultanate of Oman
6.	Antigua	47.	Dem. Rep. Of Congo	88	Japan	129.	Nigeria	170.	Suriname
7.	Argentina	48.	Denmark	89	Jordan	130.	North Korea	171.	Swaziland
8.	Armenia	49.	Djibouti	90	Kazakhstan	131.	Norway	172.	Sweden
9.	Australia	50.	Dominica	91	Kenya	132.	PAHO	173.	Switzerland
10.	Austria	51.	Dominican Rep.	92	Kiribati	133.	Pakistan	174.	Syria
11.	Azerbaijan	52.	East Timor	93	Kosovo	134.	Palestine	175.	Taiwan
12.	Bahamas	53.	Ecuador	94	Kuwait	135.	Panama	176.	Tajikistan
13.	Bahrain	54.	Egypt	95	Kyrgyzstan	136.	Papua New Guinea	177.	Tanzania
14.	Bangladesh	55.	El Salvador	96	Laos	137.	Paraguay	178.	Thailand
15.	Barbados	56.	England	97	Latvia	138.	Peru	179.	The Netherlands
16.	Belarus	57.	Equatorial Guinea	98	Lebanon	139.	Philippines	180.	Togo
17.	Belgium	58.	Eritrea	99	Lesotho	140.	Poland	181.	Tonga
18.	Belize	59.	Estonia	100	Liberia	141.	Portugal	182.	Trinidad & Tobago
19.	Benin	60.	Ethiopia	101	Libya	142.	Puerto Rico	183.	Tunisia
20.	Bermuda	61.	Fiji Islands	102	Lithuania	143.	Qatar	184.	Turkey
21.	Bhutan	62.	Finland	103	Luxembourg	144.	Rep. of South Africa	185.	Turkmenistan
22.	Bolivia	63.	France	104	Macau	145.	Rep. of Yemen	186.	Turk & Caicos
23.	Bosnia Herzegovina	64.	Gabon	105	Macedonia	146.	Romania	187.	Uganda
24.	Botswana	65.	Gambia	106	Madagascar	147.	Russian Federation	188.	Ukraine
25.	Brazil	66.	Georgia	107	Malawi	148.	Rwanda	189.	UNHCR
26.	British Virgin islands	67.	Germany	108	Malaysia	149.	Samoa	190.	UNICEF
27.	Brunei	68.	Ghana	109	Maldives	150.	Sao Tome & Principe	191.	United Arab Emirates
28.	Bulgaria	69.	Grand Cayman	110	Mali	151.	Saudi Arabia	192.	United kingdom
29.	Burkina Faso	70.	Greece	111	Malta	152.	Senegal	193.	Uruguay
30.	Burundi	71.	Grenada	112	Marshall islands	153.	Serbia & Montenegro	194.	Uzbekistan
31.	Cambodia	72.	Guatemala	113	Mauritania	154.	Seychelles	195.	Vanuatu
32.	Cameroon	73.	Guinea	114	Mauritius	155.	Sierra Leone	196.	Vatican City
33.	Cape Verde	74.	Guinea Bissau	115	Mexico	156.	Singapore	197.	Venezuela
34.	Caymon Islands (E)	75.	Guyana	116	Moldova	157.	Slovakia	198.	Vietnam
35.	Central African Rep.	76.	Haiti	117	Mongolia	158.	Slovenia	199.	Western Samoa
36.	Chad	77.	Holland	118	Montseraat	159.	Solomon islands	200.	WHO
37.	Chile	78.	Honduras	119	Morocco	160.	Somalia	201.	Yugoslavia
38.	China	79.	Hong Kong	120	Mozambique	161.	South Korea	202.	Zambia
39.	Colombia	80.	Hungary	121	Myanmar	162.	Spain	203.	Zimbabwe
40.	Comoros	81.	Indonesia	122	Namibia	163.	Sri-Lanka		
41.	Congo	82.	Iran	123	Nauru	164.	St. Kitts		

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Licensing Authority cum Drug Controller * Himachal Pradesh *

08 MAR 2022