Digitally signed by Susarencu Svetlana
Date: 2023.09.27 07:05:34 BST
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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	:	**Hisone-20** **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 ? If no ,explain:	:	Yes

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

03 MAR 2022