

HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH -173205
CERTIFICATE OF A PHARMACEUTICAL PRODUCT¹

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

No. of Certificate : HFW-H [Drugs] 185/05/23-223 Valid Upto 10.07.2025
Exporting (certifying) Country : INDIA
Importing (requesting) Country : Annexure-I
1. Name and Dosage form of Product : Mesna Injection (2 mL , 4 mL)
1.1 Active ingredient (s)² and Amount (s) per unit dose³ : Each ml Contains:-
Mesna BP-----100 mg
Water For Injections BP-----q.s.

For Complete Qualitative Composition Including Excipients: NA
1.2 Is this Product licensed to be placed on the market for use in the exporting country?⁵
Yes No
1.3 Is this product actually on the market in 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.⁶

<p>2A.</p> <p>A.1 No. of Product Licence⁷ : MB/05/158 in form No. 28 And date of Issue : 20.08.2020</p> <p>A.2. Product Licence holder : M/s Health Biotech Ltd. Vill. Sandoli, Nalagarh Road, Baddi, Distt. Solan [H.P.] India</p> <p>A.3. Status of the Product-license Holder⁸ : a. <input checked="" type="checkbox"/> b. c.</p> <p>A.3.1 For Categories b and c, The name and address of the Manufacturer producing the dosage form are⁹ Not Applicable</p> <p>A.4. Is summary Basis of approval appended?¹⁰ : YES NO <input checked="" type="checkbox"/></p> <p>A.5. Is the attached, officially approved product information complete and consonant with the licence?¹¹ : YES NO Not Approved <input checked="" type="checkbox"/></p> <p>A.6. Applicant for certificate if different from License holder¹²:</p>	<p>2. B.</p> <p>B. 1. Applicant for Certificate (name and address)</p> <p>B.2. Status of the Applicant: a. b. c. B.2.1. For categories b and c the name and address of the manufacture producing the dosage form are</p> <p>B.3. Why is marketing authorization lacking? Not Required Not Requested Under Consideration Refused</p> <p>B.4. Remark¹³:</p>
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3. Does the certifying authority arrange for periodic inspection of the Manufacturing plant in which the dosage form is produced : YES NO Not Applicable¹⁴
If No or Not Applicable, proceed to Question 4

3.1 Periodicity of routine inspection (Years) : Once in a Year

3.2 Has the manufacturer of this type of dosage form been inspected? : YES NO

3.3 Do the facilities and operations conform to GMP as recommended By the World Health Organization?¹⁵ : YES NO Not Applicable

4. Does the information submitted by the applicant satisfy the certifying Authority on all aspects of the manufacture of the product?¹⁶ : YES NO
If No, explain:

Address of Certifying Authority:

State Drugs Controller
Controlling Cum Licensing Authority
Baddi Distt. Solan (H.P.) 173205, India
01795 244288, sdc4hp@gmail.com



Name of the Authorized Person: Mr. Navneet Marwaha.

Designation : State Drugs Controller

Signature
Stamp and Date

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H. P.)-173205
11795-244288, sdc4hp@gmail.com

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ANNEXURE-I

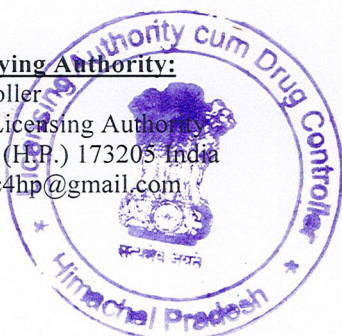
No. of Certificate: HFW-H [Drugs] 185/05/23-223
Product Name : Mesna Injection (2 ml , 4 ml)
Each ml Contains:-
Mesna BP-----100 mg
Water For Injections BP-----q.s.

Under License No: MB/05/158 in form No. 28
For Following Countries:

1	ALGERIA	31	MOZAMBIQUE	61	FIJI	91	SAUDI ARABIA	121	LIBYA	151	VIETNAM
2	AUSTRALIA	32	MONACO	62	FRANCE	92	SEYCHELLES	122	LUXEMVOURG	152	VIRGIN ISLAND
3	ARMENIA	33	MONGOLIA	63	FRENCH GUIANA	93	SEIRALEONE	123	LAOS	153	YEMEN
4	AUSTRIA	34	NEPAL	64	GABON	94	SLOVENIA	124	MUSCAT	154	YUGOSLAVIA
5	ARGENTINA	35	NIGERIA	65	GHANA	95	SOLOMON ISLANDS	125	MALWAI	155	ZAIRE
6	AZERBAUAN	36	NICARAGUA	66	GUATEMALA	96	SOMALI	126	MAURITIUS	156	ZAMBIA
7	BAHRAIN	37	NORWAY	67	GEORGIA	97	SOMALIA	127	MALDOVIA	157	ZIMBABWE
8	BELARUS	38	NETHERLANDS	68	GERMANY	98	SOUTH KOREA	128	MOROCCO	158	Ecuador
10	BURKINA FASO	40	NEWZEALANDS	70	GREECE	100	SURINAM	130	MALAYSIA	159	DOMNICAN REPUBLIC
12	BRAZIL	42	OMAN	72	HUNGARY	102	SWEDEN	132	MAURITANIA		
13	BAHAMAS	43	PHILIPPINES	73	HONGKONG	103	SYRIA	133	MADAGASKAR		
14	BANGLADESH	44	PANAMA	74	HONDURAS	104	SLOVAK REPUBLIC	134	MALDIVES		
15	BARBADOS	45	PERU	75	HAITI	105	SWITZERLAND	135	MALIA		
16	BOLIVIA	46	PAKISTAN	76	HAWAI	106	TANZANIA	136	MALIA		
17	BULGARIA	47	PAPUA-NEW GUINEA	77	ICELAND	107	JORDAN	137	TOGO		
18	BOTSWANA	48	PARAGUAY	78	IRAN	108	JAMAICA	138	THAILAND		
19	CAMEROON	49	PORTUGAL	79	IRAQ	109	JAPAN	139	TRINIDAD & TOBAGO		
20	CZECH REPUBLIC	50	POLAND	80	IVORY COAST	110	KAZAKHSTAN	140	TUNISEA		
21	CAMBODIA	51	PUERTO RICO	81	INDONESIA	111	KENYA	141	TAIWAN		
22	CHINA	52	QATAR	82	IRELAND	112	KOSOVO	142	TURETKY		
23	COLUMBIA	53	ROMANIA	83	ITALY	113	KUWAIT	143	U.A.E		
24	COSTARICA	54	DOMINICAN REPUBLIC	84	RUSSIA	114	KOREA	144	UGANDA		
25	CIS	55	DENMARK	85	RWANDA	115	LIECHTENSTEIN	145	UNITED KINGDOM		
26	CONGO	56	EGYPT	86	SRILANKA	116	LEBANON	146	UKRANE		
27	CHILE	57	ESTONIA	87	SNEGAL	117	LATVIA	147	UZBEKISTAN		
28	CANADA	58	ETHOPIA	88	SOUTH AFRICA	118	LITHUANIA	148	U.S.A		
29	CUBA	59	EL-SALVADOR	89	SUDAN	119	LESOTHO	149	URUGUAY		
30	CYPRUS	60	FINLAND	90	SINGAPORE	120	LIBERIA	150	VENEZULEA		

Address of Certifying Authority:

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