CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 04** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**
Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **L-Asparaginase for Injection 10000 IU (Lyophilized)**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each vial contains:**

L-Asparaginase	10000 IU
Excipients	qs

(Sterile lyophilized powder for reconstitution)

For complete qualitative composition including excipients, see attached.[4] 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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MB/09/749**
and date of issue : **13.11.2019**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.) INDIA**

A.3 Status of product license Holder[8]

a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?**[10]

Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]

Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :

a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking

Not Required	Not Requested	under consideration	refused
[ ]	[ ]	[ ]	[ ]

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

03 JAN 2023

Name of the Authorized Person: Navneet Marwaha

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

Signature:
Stamp and date:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 49** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **PEG L-Asparaginase Injection 3750 IU/5 ml**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each ml contains:**
PEG L-Asparaginase 750 IU
Excipients qs

For complete qualitative composition including excipients, see attached.[4] 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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MB/09/749**
and date of issue : **05.03.2020**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.) INDIA**

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking
[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

05 JAN 2023

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

Name of the Authorised Person: Navneet Marwaha
(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi, Distt.Solan (H. P.)-173205
01795 244288, sdc4hp@gmail.co
Signature:
Stamp and date:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 36** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **Sorafenib Tablets 200 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each film coated tablet contains:**

Sorafenib Tosylate	
eq. to Sorafenib	200 mg
Excipients	qs
Colour: Approved colours	

For complete qualitative composition including excipients, see attached.[4]

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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MNB/09/748**
and date of issue : **25.02.2021**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.) INDIA**

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking
[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

05 JAN 2023

Name of the Authorised Person: Navneet Marwaha
(NAVNEET MARWAHA
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt. Solan (H.P.)-173205
01795-244288, sdc4hp@gmail.com)

Signature:

Stamp and date:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 44** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **Thalidomide Capsules USP 100 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each hard gelatin capsule contains:**
Thalidomide USP 100 mg
Excipients qs
Approved colours used in empty capsule shell

For complete qualitative composition including excipients, see attached.[4] 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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MNB/09/748**
and date of issue : **13.11.2019**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.) INDIA**

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking
[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

05 JAN 2023

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

Name of the Authorised Person: Navneet Marwaha
NAVNEET MARWAHA
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com
Signature:
Stamp and date:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 37** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **Temozolomide Capsules USP 20 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each hard gelatin capsule contains:**

Temozolomide USP	20 mg
Excipients	qs
Approved colours used in empty capsule shell	

For complete qualitative composition including excipients, see attached.[4] 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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MNB/09/748**
and date of issue : **06.04.2021**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.). INDIA**

A.3 Status of product license Holder[8]

a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**

Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]

Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :

a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking

[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

Address of certifying authority:

State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

05 JAN 2023

Name of the Authorised Person: Navneet Marwaha

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H. P.)-173205

Signature:

Stamp and date:

NO. HFW –H (Drugs) 22/05 (Vol. VIII)
Health and Family Welfare Department
Himachal Pradesh
Baddi-173 205,

Date :

FREE SALE CERTIFICATE

This is to certify that M/s Adley Formulations, Village Kotla, Barotiwala, Distt. Solan, HP are holding Licence in Form No. 25 & 28 and bearing Manufacturing License No. MNB/05/99 & MB/05/100 granted on dated 19.03.2020 and valid up to 08.02.2025 issued by the Drugs Control Administration for the manufacture for sale or distribution of drugs approved by this department as per the provisions of Drugs and Cosmetics Act, 1940 and rules made there under the said Licenses , the firm is permitted to manufacture the following drugs subject to the provisions of Drugs and Cosmetics Act, 1940 and rules there under and to export freely subject to the Laws and Regulations of the importing country.

Assistant Drugs Controller HP Baddi Distt.Solan-173205

19/3/2020

(Dr. KAMLESH NAIK)
ASSISTANT DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI, DISTRICT SOLAN H.P. 173205
E mail:adchp@gmail.com

Assistant Drugs Controller
Licensing Authority -Cum-
Controlling Authority,
H.P. Baddi-173205

LIST OF ONCOLOGY LYOPHILIZED PRODUCTS

Sr. No.	GENERIC NAME	LABEL CLAIM	STRENGTH
1.	Gemcitabine for Injection USP	Each Vial Contains: Gemcitabine Hydrochloride USP eq. to Gemcitabine 200 mg Excipients qs. (Sterile Lyophilized Powder for reconstitution)	200 mg per Vial
2.		Each Vial Contains: Gemcitabine Hydrochloride USP eq. to Gemcitabine 1000 mg Excipients qs. (Sterile Lyophilized Powder for reconstitution)	1000 mg per Vial
3.	Zoledronic Acid for Injection	Each Vial contains:- Zoledronic Acid monohydrate eq. to Zoledronic Acid anhydrous 4.0 mg Excipients qs. (Sterile Lyophilized Powder for reconstitution)	4.0 mg per Vial
4.	Dacarbazine For Injection	Each Vial contains: Dacarbazine USP 200 mg Excipients qs. (Sterile Lyophilized Powder for reconstitution)	200 mg per Vial
5.	Dacarbazine For Injection	Each Vial contains: Dacarbazine USP 500 mg Excipients qs. (Sterile Lyophilized Powder for reconstitution)	500 mg per Vial

Assistant Drugs Controller (H.P.) Baddi Distt. Solan-173205

9/3/2020

(Dr. KAMLESH NAIK)
ASSISTANT DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o ASSISTANT DRUGS CONTROLLER
BADDI DISTRICT SOLAN,H.P.-173205
E mail:ddc4hp@gmail.com
Phone : 01795-244288

Assistant Drugs Controller
Licensing Authority Cum-
Controlling Authority,
H.P. Baddi-173205

NO .HFW-H (DCA) (Vol. 1) 98/09
HEALTH AND FAMILY WELFARE DEPARTMENT
BADDI, HIMACHAL PRADESH

FREE SALE CERTIFICATE

This is to certify that M/s Beta Drugs Ltd. Situated at Kharuni – Lodhimajra Road, Village: Nandpur, Baddi, Distt Solan (H.P.) are holding license/s in form/s No 25 & 28. bearing No. MNB/09/748 & MB/09/749 respectively valid up to 26.10.2024 issued by the Drugs Control Administration for the manufacture for sale or distribution of drugs approved by this department as per the provisions of Drugs and Cosmetics Act, 1940 and rules made there under the said Licenses , the firm is permitted to manufacture the following drugs subject to the provisions of Drugs and Cosmetics Act, 1940 and rules there under and to export freely subject to the Laws and Regulations of the importing country.

List of Product as enclosed as **ANNEXURE I**

10-8-19

(NAVNEET MARWAHA)
State Drugs Controller
Cum- Licensing Authority,
H.P. Baddi-173205

State Drugs Controller cum Licensing Authority
Baddi Distt Solan (H.P.)-173205
01795-244286,sdc4hp@gmail.com

NO .HFW-H (DCA) (Vol. 1) 98/09
HEALTH AND FAMILY WELFARE DEPARTMENT
BADDI, HIMACHAL PRADESH

ANNEXURE I
LIST OF PRODUCTS

14.	Dasatinib Tablets 50mg	Each film coated tablet contains: Dasatinib 50mg Excipients qs Colour : Red oxide of iron	50 mg
15	Dasatinib Tablets 70mg	Each film coated tablet contains: Dasatinib 70mg Excipients qs Colour : Titanium Dioxide	70 mg
16.	Vinorelbine Injection USP 50 mg / 5 ml	Each ml contains: Vinorelbine Tartrate USP eq. to Vinorelbine 10mg Water for Injections USP qs	50 mg / 5 ml

10.8.17

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

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 31** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **Dasatinib Tablets 50 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each film coated tablet contains:**

Dasatinib	50 mg
Excipients	qs
Colour: Red Oxide of Iron	

For complete qualitative composition including excipients, see attached.[4] NA

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] **Yes** [x] **No** [ ]

1.3 Is this product actually on the market in the exporting country? Yes [x] **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 continue section 2B[6]

2A

A.1 Number of product license[7] **MNB/09/748**
and date of issue : **03.07.2021**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.) INDIA**

A.3 Status of product license Holder[8]
a [x] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?**[10]
Yes [ ] No [x]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [x]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status **of application :**
a [ ] b [ ] c [ ] d [ ]

B.2.1 For **categories b and c the name** and address of the **manufacturer producing the dosages** form are[9]

B.3 Why **is marketing authorization lacking**

Not Required	Not Requested	under consideration	refused
[ ]	[ ]	[ ]	[ ]

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing **plant in which the dosage form is** produced?
Yes [x] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [x] **No** [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World **Health Organisation?**[15]
Yes [x] 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 [x] No [ ] Not applicable [ ]

If no, explain:

03 JAN 2023

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

Name of the Authorized Person: Navneet Marwaha
State Drugs Controller
Controlling cum Licensing Authority
Baddi, Distt. Solan (H.P.)-173205
Signature:
Stamp and date:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (DRUG) 22/05 (Vol. VII)/ 23 - 43** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **Fludarabine Phosphate for Injection USP 50 mg (Lyophilized)**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each vial contains:**
Fludarabine Phosphate USP 50 mg
Excipients qs
(As sterile lyophilized powder for reconstitution)

For complete qualitative composition including excipients, see attached.[4] 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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MB/09/749**
and date of issue : **13.11.2019**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur Baddi, Distt. Solan (H.P.). INDIA**

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking
[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

05 JAN 2023

Address of certifying authority:
State Drugs Controller,
Licensing Authority-cum -Controlling Authority
Baddi - 173205, Distt- Solan (H.P), INDIA
Ph. No.: 01795 244288
Fax. No. 01795 244288

Name of the Authorised Person: Navneet Marwaha
(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Distt.Solan (H.P.)-173205
sdc4hp@gmail.com
Signature :
Stamp and date:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 46** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **HYDROXYUREA CAPSULES USP 500 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each hard gelatin capsule contains:**
Hydroxyurea USP 500 mg
Excipients qs
Approved colours used in empty capsule shell

For complete qualitative composition including excipients, see attached.[4] 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 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 continue section 2B[6]

2A

A.1 Number of product license[7] **MNB/09/748**
and date of issue : **13.11.2019**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.). INDIA**

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

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

B.2 Status of application :
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking
[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[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 [x] No [ ] Not applicable [ ]

If no, explain:

05 JAN 2023

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

Name of the Authorised Person: Navneet Marwaha
(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

Signature:

Stamp and date:

NO. HFW –H (Drugs) 22/05 (Vol. VIII)
Health and Family Welfare Department
Himachal Pradesh
Baddi-173 205,

Date :

FREE SALE CERTIFICATE

This is to certify that M/s Adley Formulations Pvt. Ltd, Village Kotla, Barotiwala, Distt. Solan, HP are holding Licence in Form No. 25 & 28 and bearing Manufacturing License No. MNB/05/99 & MB/05/100 granted on dated 19.03.2020 and valid up to 08.02.2025 issued by the Drugs Control Administration for the manufacture for sale or distribution of drugs approved by this department as per the provisions of Drugs and Cosmetics Act, 1940 and rules made there under the said Licenses , the firm is permitted to manufacture the following drugs subject to the provisions of Drugs and Cosmetics Act, 1940 and rules there under and to export freely subject to the Laws and Regulations of the importing country.

Sr. No	Drug Product	Composition	Ph. Ref	Strength
1	Sorafenib Tablets 200 mg	Each film coated tablet contains: Sorafenib Tosylate Eq. to . Sorafenib 200 mg Excipients qs Colour : Approved colours	IH	200 mg
2	Bleomycin Injection USP 15Units (Lyophilized)	Each single dose vial contains : Bleomycin Sulphate USP eq. to Bleomycin 15 Units (As sterile freeze dried powder for reconstitution)	USP	15 Units

12.8.24

State Drug Controller
Controlling Cum- Licensing Authority,
H.P. Baddi-173205

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