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) 828/12 / 18 - 16 VALID UPTO: 08.02.2020
Exporting (certifying) country : INDIA
Importing (requesting) country : BOSNIA

1. Name and dosage form of product : **ZOVORIN - 30**
Leucovorin Calcium Injection USP 30 mg/3 ml

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

Leucovorin Calcium	USP	
Eq. to Leucovorin		10 mg
Sodium Chloride	USP	8 mg
Propylparaben Sodium	USNF	0.02 % w/v
Methylparaben Sodium	USNF	0.08 % w/v
Water for Injection	USP	qs

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

1.2 Is this product licenced 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] and date of issue
No :- L/12/1149/MB 28-A Dated:- 27/10/2017

A.2 Product license holder: (Name & address)
M/s FLAGSHIP BIOTECH INTERNATIONAL
Village-Kotla, Barotiwala.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 licence holder [12] **Flagship Biotech USA Inc.**
8180 NW 36 Street, STE 100 City Of Doral,
State Of Florida-33166.USA

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:

Digitally signed by Margină Veaceslav
Date: 2019.03.05 11:29:26 EET
Reason: MoldSign Signature
Location: Moldova

28-12-18

Address of certifying authority:
State Drugs Controller,
Licensing Authority-cum -Controlling Authority
Baddi - 173205, Distt- Solan (H.P), INDIA
P. 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: