CERTIFICATE OF PHARMACEUTICALS PRODUCTS

This Certificate confirms to the format recommended by the World Health Organization (General Instruction and explanatory notes attached)

No. of Certificate	:	**Mfg./WHO-COPP /Globela/2021**
Exporting (Certifying) country	:	**INDIA**
Importing (requesting) country	:	**VIETNAM** 001072
1 Name and dosage form of product	:	**GLOMIDE 100** (Thalidomide Capsules USP 100 mg)

Active ingredient (S)[2] and amount (s) per unit dose[3] : Composition :
Each hard gelatin capsule contains:
Thalidomide USP.....100 mg
Excipients.....Q.S.
Approved color used in capsule shell.

Active Ingredients & Excipients – Annexure I attached.

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 1.2 is yes, continue with section 2 A and omit section2 B
If the answer to 1.2 is no, omit section 2 A and Continue section 2 B[6]

2 A

A.1 Number Of product license [7] and date of issue form 25: G/25/1749,
Date :22/03/2021

A.2 Product License holder :
M/S, GlobelaPharma Pvt. Ltd
357-358, GIDC, Sachin, Surat – 394 230

A.3 Status of product – license Holder [8] :
Manufacturer of finished dosage form
a ☑ b ☐ c ☐

A.3.1 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 approve 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**

2 B

B.1 Application for certificate (name and address)

B.2 Status of applicant : a ☐ b ☐ c ☐ d ☐

B.2.1 For categories 'b' and 'c' the name and address of the Manufacturer producing the dosage form are [8]

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): Once in a Year

3.2 Has the manufacture of this type of dosage form been inspected? Yes ☑ No ☐

3.3 Do the facilities and operations confirm to GMP as recommended by 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 ?[15] Yes ☐ No ☐ Not Applicable: ☑

This certificate is valid up to: 14/09/2024

Address of certifying authority:
Commissioner of Food & Drugs Control Administration
Gujarat State,
Dr. Jivraj Mehta Bhavan,
Block No. 8, old Sachivalaya,
Gandhinagar – 382 010.
Telephone / fax numbers:
Tel : 079 – 23253400/ Fax : 079 – 23253399

Name of the authorized person: Mr. H L. Ravat
Signature :
Stamp and date:

Joint Commissioner
Food & Drugs Control Administration
Gujarat state .

- 5 JAN 2022

Digitally signed by Chitic Ecaterina
Date: 2022.09.18 22:18:31 EEST
Reason: MoldSign Signature
Location: Moldova

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 handwritten.

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 single products only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use whenever possible, International Nonproprietary Names (INNS) or national nonproprietary names.
3. The formula (complete composition) of 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 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. Section 2A and 2B are mutually exclusive.
7. Indicate when applicable, if the license is provisional, on the product has not yet been approved
8. Specify whether the person responsible for placing the product on the market. :
   (a) Manufactures the dosage form :
   (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 products 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 authority that summarizes 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 these circumstances, permission for 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 non 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 active ingredient.
    e) Any other reasons please specify.
14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirement for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty second report of the Expert Committee on Specification for Pharmaceutical Preparation WHO Technical Report Series No.823, 1992 Annex I. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 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[8]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.

ANNEXURE-1

Name and dosage form of product : Thalidomide Capsules USP 100 mg
GLOMIDE 100

Active ingredient (s) and Amount (s) per unit dose : Each hard gelatin capsule contains:
Thalidomide USP.....100 mg
Excipients.....Q.S.
Approved color used in capsule shell.

Sr. No:	Ingredients	Specification	Label Claim	Qty./Cap (mg)	Qty./ Batch (kg)	Function
1.	Thalidomide	USP	100	100.000	1.000	Active
2.	Maize Starch	BP	---	156.000	1.560	Diluent
3.	Talcum	BP	---	15.000	0.150	Glidant
4.	Dibasic Calcium Phosphate	BP	---	250.000	2.500	Filler
5.	Colloidal Silicon Dioxide (Light)	BP	---	5.000	0.050	Glidant
Average wt. of Net Content				**526.00**	**Limit: 526.00 mg ± 7.5 %**	
6.	E.H.G. Capsules SIZE "0" Dark Blue/ Light Blue	IH	---	97.000	10.200 thou	Capsule shell
Average wt. of Capsule				**623.00**	**Limit: 623.00 mg ± 7.5 %**	

NOTE: Active material is to be calculated on Assay / Potency basis.
*Does not appear in the finished Product.
IHS = In-House Specification
BP = British Pharmacopoeia
USP=United States Pharmacopeia

****Composition of E.H.G. Capsule:**

Sr. No.	Name of Ingredients	Reference	% Quantity
1.	Gelatin	IP	Qs to 100
2.	Water Content	USP,EP,IP	14.30-14.80
3.	Methyl Peraben	IP	0.100
4.	Propyl Peraben	IP	0.025
5.	Povidone (PVPK 30)	IP	0.100
6.	Sodium Lauryl Sulphate	IP	0.100
7.	Silicon Dioxide	IP	0.063
Cap (%)			
8.	Titanium Dioxide	CI.NO-77891,E 171	1.764
9.	Brilliant Blue	CI.NO-42090,E 133	0.231
Body (%)			
10.	Titanium Dioxide	CI.NO-77891,E 171	0.604
11.	Brilliant Blue	CI.NO-42090,E 133	0.393
12.	Erythrosine	CI.NO-45430,E 127	0.049