World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: TB304-0/MS/ADV

Your reference:

Mr Imtiyaz Basade
Sr. Vice-President, Regulatory Affairs
Mylan Laboratories Ltd
Plot No.564/A/22 Road No. 92
Jubilee Hills
Hyderabad 500096
Telangana
Inde

12 December 2017

Dear Mr Basade,

WHO Prequalification Team – Medicines Assessment
FPP Prequalification – Letter of Prequalification

Application number: TB304-0

I refer to your letter expressing Mylan Laboratories Ltd's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and published in the WHO Technical Report Series No. 908, and amended subsequently in the Forty-fifth report, as published in the WHO Technical Report Series No. 961 in 2011.

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- **TB304 - Cycloserine Capsules, hard 250mg**

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

ENCLS: (2)

.../...

Digitally signed by Dicusar Vladimir
Date: 2021.09.02 09:05:00 EEST
Reason: MoldSign Signature
Location: Moldova

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and
- submit the respective information about the intended variations and the required additional data by email to **prequalassessment@who.int**, and in hard copy, clearly marked as indicated, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref Number: TB304

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Mylan Laboratories Ltd and the WHO Prequalification Team – Medicines, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Mylan Laboratories Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
HIS/EMP/RHT/PQT Room 613
20 Avenue Appia
1211 Geneva 27
Switzerland

I look forward to receiving this information from within two weeks of the date of this letter at the latest. For further information please use the email address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 20 DEC 2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).
Certificate No.: **NEW-WHO-GMP/CERT/AD/72573/2018/11/26257**

On the basis of the inspection carried out on **20/6/2018 & 21/06/2018, 24/9/2018 & 25/9/2018** ,we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **MYLAN LABORATORIES LIMITED**
   Address : **PLOT NO. H-12 & H-13, MIDC, WALUJ, AURANGABAD 431136 MAHARASHTRA STATE, INDIA**
2. Licence No. : **AD089 In Form 25, AD064 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 17 Dec 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1LYM2447257320181218

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:18 Dec 2018

18 DEC 2018

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
   List the dosage forms, starting materials, categories and activities. Examples are given below.

   Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

   Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

   Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/72573/2018/11 /26257 **VALID UP TO :17 Dec 2021**

Name of Manufactring Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
1	Abacavir Sulfate and Lamivudine Dispersible Tablets 120mg/60mg	Each dispersible tablet contains : Abacavir Sulfate USP equivalent to Abacavir 120 mg Lamivudine USP 60 mg
2	Acyclovir Tablets USP 400mg	Each tablet contains: Aciclovir Ph.Eur 400 mg
3	Atazanavir (as Sulfate) Capsules 150 mg	Each capsule contains: Atazanavir (as sulfate) equivalent to Atazanavir IH 150 mg Colour:FD&C Blue #2
4	Atazanavir (as sulfate) Capsules 300mg	Each capsule contains : Atazanavir sulfate equivalent to Atazanavir IH 300.00 mg
5	Clarithromycin Tablets, BP 500mg	Each film coated tablet contains: Clarithromycin Ph.Eur 500 mg
6	Cycloserine Capsules USP 250mg	Each Capsule contains: Cycloserine USP 250 mg
7	Darunavir Tablets 600mg	Each film coated tablet contains : Darunavir Ethanolate equivalent to Darunavir 600 mg
8	Efavirenz Tablets IP 600mg	Each film coated tablet contains : Efavirenz IP 600 mg Colour:Yellow Iron Oxide, Iron Oxide Red

1 2 3 4 5 6

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1LYM244725732018121B

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:18 Dec 2018

18 DEC 2018

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : **COPP/CERT/AD/80951/2019/11/26582/137723** **Valid Upto :17 Dec 2021**

Exporting Country : INDIA

Importing Country : **As per Annexure**

1. Name and dosage form of product : **Cycloserine Capsules USP 250mg**

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

Cycloserine USP 250 mg

For complete qualitative composition including excipients :[4] As per Annexure

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 ☐

2A.1 Number of product license:[7] **AD064 In Form 28**
and date of issue: **01 Feb 2012**

2A.2 Product License holder (Name and address) :
MYLAN LABORATORIES LIMITED PLOT NO. H-12 & H-13, MIDC, WALUJ, AURANGABAD 431136 MAHARASHTRA STATE, INDIA

2A.3 Status of product-license Holder :[8]
A ☒ B ☐ C ☐

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:[9]

2A.4 Is summary basis of Approval appended ?[10]
Yes ☐ No ☒

2A.5 Is the attached, officially approved product information complete and consonant with the license ?[11]
Yes ☐ No ☐ Not Provided ☒

2A.6 Applicant for certificate if different from License holder :[12]
Not Applicable

2B.1 Applicant for certificate (name and address) :

2B.2 Status of applicant :
A ☐ B ☐ C ☐

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ Refused

2B.4 Remarks :[13]

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** ☒ **No** ☐ **Not Applicable**[14] ☐

3.1 Periodicity of routine inspections(years) : **Once a year**

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 [14] ☐

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 :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax: +91-22-26591959

5LYM244809512019011805 9

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:18 Jan 2019

18 JAN 2019

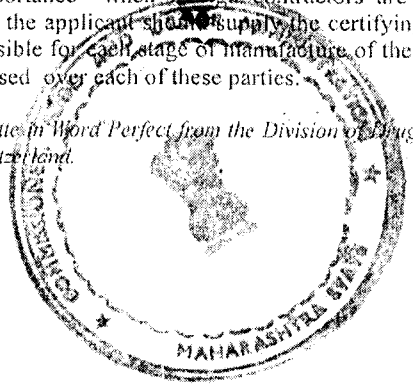
GENERAL INSTRUCTION :

Please refer to the guidelines for full instruction 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 hand written.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 a single product 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 the 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-Licence 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 Licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the Licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market :
   (a) manufactures the dosages 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 - Licence 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 product Licence. If the production site is changed the Licence must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the 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 this circumstance, permission for issuing the certificate is required from the product Licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not 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 dosage limit for an active ingredient
   (e) any other reason, 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 requirements for good practices in the manufacture and quality control of drugs referred to the certificate are those included in the thirty- second report of the Expert Committee on specifications for Pharmaceutical Preparations (WHO Technical Report Series, No.823 , 1992 , Annex 1) 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. The Section is to be completed when the product - licence 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.

The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.



Food & Drugs Administration, Maharashtra State, Mumbai 400051, India

Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : COPP/CERT/AD/80951/2019/11/26582/137723

Valid up to: 17 Dec 2021

Name of the Product License Holder : MYLAN LABORATORIES LIMITED PLOT NO. H-12 & H-13, MIDC, WALUJ, AURANGABAD 431136 MAHARASHTRA STATE, INDIA

Name of the Product : Cycloserine Capsules USP 250mg

List of Countries For Export

Afghanistan	Brunei	Ecuador	Hong-Kong	Lithuania	Nigeria	Sierra Leone	Togo
Albania	Brunei Darussalam	Egypt	Hungary	Luxembourg	North Korea	Singapore	Tongo
Algeria	Bulgaria	El Salvador	Iceland	Macau	Norway	Slovakia	Trinidad & Tobago
Andorra	Burkina Faso	England	India	Macedonia	Oman	Slovenia	Tunisia
Anglia	Burundi	Equatorial Guinea	Indonesia	Madagascar	PAHO	Solomom Island	Turkey
Angola	Cabo Verde	Eritrea	Iran	Malawi	Pakistan	Somalia	Turkmenistan
Anguilla	Cambodia	Estonia	Iraq	Malaysia	Palau	South Africa	Turks and Calicos
Antigua	Cameroon	Ethiopia	Ireland	Maldives	Palestine	South Korea	Tuvalu
Antigua and Barbuda	Canada	Fiji	Israel	Mali	Panama	South Sudan	Uganda
Argentina	Cape Verde	Fiji Island	Italy	Malta	Papua New Guinea	Spain	Ukraine
Armenia	Cayman Island	Finland	Ivory Coast	Marshal Island	Paraguay	Sri Lanka	UNHCR
Aruba	Central African Republic	France	Jamaica	Mauritania	Peru	St. Kitties	UNICEF
Australia	Chad	French Guiana	Japan	Mauritius	Philippines	st. Kitties and Nevi	United Arab Emirates
Austria	Chile	Gabon	Jordan	MCGM	Poland	St. Lucia	United Kingdom
Azerbaijan	China	Gambia	Kazakhstan	Mexico	Porte Rico	St. Maarten	United State
Bahamas	Colombia	Georgia	Kenya	Micronesia	Portugal	St. Vincent	UNOPS
Bahrain	Comoros	Germany	Kiribati	Moldova	Qatar	St. Vincent and the Grenadines	Uruguay
Bangladesh	Congo	Ghana	Korea	Monaco	R.D. Congo	Sudan	Uzbekistan
Barbados	Costa Rica	Global Fund	Kosovo	Mongolia	Rep. of Congo	Sultanate of Oman	Vanuata
Belarus	Croatia	Grand Cayman	Kurdistan	Monstserrat	Reunion	Suriname	Vatican City
Belgium	Cuba	Greece	Kuwait	Montenegro	RITES	Swaziland	Venezuela
Belize	Curacao	Grenada	Kyrgyzstan	Morocco	Romania	Swedan	Vietiane
Belorussia	Cyprus	Guatemala	LaO PDR	Mozambique	Russia	switzerland	Vietnam
Benin	Czechia	Guinea	Laos	Myanmar	Rwanda	Syria	Western Samoa
Bermuda	Czechoslovakia	Guinea-Bissau	Latvia	Namibia	Samao	Taiwan	WHO
Bhutan	Denmark	Guyana	Lebanon	Nauru	San Marino	Tajikistan	Yemen
Bolivia	Djibouti	Haiti	Leone	Nepal	Sao Tome and Principe	Tanzania	Yugoslavia
Bosnia	Dominica	Herzegovina	Lesotho	Netherlands	Saudi Arabia	Tchad	Zaire
Bosnia and Herzegovina	Dominican Republic	Holland	Liberia	New Zealand	Senegal	Thailand	Zambia
Botswana	DR Congo	Holy See	Libya	Nicaragua	Serbia	The Netherlands	Zanzibar
Brazil	East Timor	Honduras	Liechtenstein	Niger	Seychelles	Timor Leste	Zimbabwe
British Virgin							

Address of certifying authority:
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai - 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
SLYM24480951201901 6056

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:18 Jan 2019

18 JAN 2019

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

Annexure of Excipients

No. of certificate	:	COPP/CERT/AD/80951/2019/11/26582/137723 VALID UP TO :17 Dec 2021
Name of the Company	:	MYLAN LABORATORIES LIMITED PLOT NO. H-12 & H-13, MIDC, WALUJ, AURANGABAD 431136 MAHARASHTRA STATE, INDIA
Name and dosage form of product	:	Cycloserine Capsules USP 250mg

Sr.No.	Ingredients	Specification	Qty/Units
1	Cycloserine	USP	250 mg
2	Talcum	USP/NF	100 mg
3	EHGC " Size 1", Cap - Light Orange opaque, Body - White-opaque, Imprinted with "MYLAN" over "CS250" in black ink on both cap and body.		q.s.

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
5LYM2448095120190118059

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:18 Jan 2019

18 JAN 2019