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E-mail: [prequalification@who.int](mailto:prequalification@who.int)

In reply please refer to: TB365-0/MS/EG

Your reference:

CONSIDER THIS DATE



Dear Mr Basade,

**WHO Prequalification Unit – Medicines Assessment  
FPP Prequalification – Letter of Prequalification**

**Application number: TB365-0**

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:

- **TB365 - Linezolid Tablet, Film-coated 600mg**

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](http://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)

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 in electronic format (CD or DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

CONFIDENTIAL

Attention: Dr Matthias Stahl  
WHO Prequalification Unit – Medicines  
Product Ref Number: TB365

UNICEF Supply Division  
Oceanvej 10-12  
2150 Nordhavn Copenhagen  
Denmark

Please send the link to [FPPassessment@who.int](mailto:FPPassessment@who.int), if you prefer to submit the response via a file transfer link.

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. The applicant or manufacturers is obliged to pay the annual maintenance fee, first payment due when the product has been prequalified (included in the prequalified) list for 12 months, and then annually (see <https://extranet.who.int/prequal/content/prequalification-procedures-and-fees-0>). Failure to pay the annual maintenance fee will lead to the removal of the product from the prequalified 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:

WHO Prequalification Unit – Medicines Assessment  
World Health Organization  
Attention: Prequalification Secretariat  
MHP/RPQ/PQT Room 615  
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 [prequalification@who.int](mailto:prequalification@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  
Team Lead  
Prequalification Unit - Medicines Assessment  
Regulation and Prequalification Department