



Annex B. LIST AND TECHNICAL SPECIFICATIONS OF REQUESTED PRODUCTS

Eligibility criteria for submission of Bids for anti-tuberculosis medicines

Only bidders with products in compliance with the GDF Quality Assurance Policy (see <https://www.stoptb.org/suppliers/quality-assurance>) are eligible to participate in the ITB.

The requirements are as following:

A. Products pre-qualified by WHO under the WHO Prequalification Programme (WHO PQP)¹ or approved by a Stringent Regulatory Authority (SRA)²;

B. In the absence of products meeting the criteria "A" as above, products recommended for use through a quality risk/benefit assessment process by the Expert Review Panel (ERP)³. These products are eligible for procurement for a limited period of time and under the following conditions:

1. The Finished Pharmaceutical Product (FPP) must be manufactured at an approved site as follows:
 - The site must have been inspected by WHO as a part of the WHO PQP (refer to <https://extranet.who.int/pqweb/medicines>) and found to be operating at an acceptable level of compliance with WHO Good Manufacturing Practice (GMP) for the specific product; or
 - The site must have been inspected and found acceptable for the manufacture of the specific product by SRA defined as either: an International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) member country, an ICH observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement; or
 - The site must have been inspected and found acceptable for the manufacture of the specific product by inspectors of a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
2. A product approval as described under either point "A" is pending, i.e. manufacturers have submitted relevant product dossiers and the dossiers have been accepted for assessment either by WHO PQP or SRA. Approvals under point "B" shall be limited to a maximum duration of 12 months in which manufacturers should obtain approval by WHO PQP or SRA.

Note: A bid submitted for a product for which the bidder has not received regulatory approval status as per GDF Quality Assurance policy and procedures, shall not be considered for the ITB evaluation.

¹ <https://extranet.who.int/pqweb/medicines>

² <https://extranet.who.int/pqweb/medicines>

³ <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/>

Schedule 4: Bedaquiline 100mg demand for all suppliers

<i>Item No</i>	<i>Generic Code</i>	<i>General Description</i>	<i>Primary packaging</i>	<i>Secondary packaging</i>
1+2	Bdq-100-(L) and/or Bdq-100-(B)	Bedaquiline 100mg uncoated tablets, white to off white, round biconvex	Pack of 188 tablets in HDPE container or 6 or 10 tablets/blister	Pack of 188 tablets in HDPE container or pack of 4 blisters x 6 tablets or 10 blisters x 10 tablets

Schedule 5: Bedaquiline 100mg demand for originator product only

<i>Item No</i>	<i>Generic Code</i>	<i>General Description</i>	<i>Primary packaging</i>	<i>Secondary packaging</i>
1+2	Bdq-100-(L) and/or Bdq-100-(B)	Bedaquiline 100mg uncoated tablets, white to off white, round biconvex	Pack of 188 tablets in HDPE container or 6 or 10 tablets/blister	Pack of 188 tablets in HDPE container or pack of 4 blisters x 6 tablets or 10 blisters x 10 tablets