

## **Bedaquiline Tablets (Product Code-52)**

### **A. Specific requirements**

#### **Item:**

Product Code 52 (PC 52) consists of tablets of Bedaquiline-100mg. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

### **B. Description:**

Bedaquiline tablets shall conform to the general requirements of tablets and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Each uncoated tablet of Bedaquiline contains: Bedaquiline - 100mg

The quality of Bedaquiline should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

#### **Protocols and Testing:**

The supplier has to share all testing protocols and procedures being followed for the analysis of drug and will have to share Certificate of Analysis of each batch with the purchaser.

### **C. Quality Assurance:**

#### **Compliance:**

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f) the product shall meet the quality standards as required under WHP PQP / SRA / Evaluated to meet the quality standards by an Expert Review Panel (ERP).

**Evidence:**

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The Supplier shall provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

**Inspection:**

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, warehouse, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

**Testing:**

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on the product.

**D. Storage:**

Do not store above 30° C.

Keep out of the sight and reach of children. Store in the original container or package in order to protect from moisture.

**E. Shelf Life:**

Shelf life should be minimum 36 months from the date of manufacture.

**At least 5/6<sup>th</sup> of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse.**

The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

**F. Qualification of the Manufacturer:**

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products.

**Recalls:**

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

## **G. Packaging**

The drug is initially packed in a white high density polyethylene (HDPE) bottle with child-resistant polypropylene (PP) closure with induction seal liner. Each HDPE bottle shall contain 188 tablets of Bedaquiline-100mg.

25 such HDPE bottles would be further packed in white coloured Millboard/Grey board boxes and 42 such Millboard / Greyboard boxes are ultimately packed in a 5-Ply Shipper.

Quality Assurance is according to Norm ISO 9001 for all the packaging material.

### **Millboard/ Grey board Box:**

Each box shall contain 25 HDPE bottles of Bedaquiline-100mg. Each Millboard / Grey board box shall be labeled and fabricated from at least 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

The **Millboard/ Grey board Box** shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Product Name / content
- Product Strength
- Batch Number of the drug
- Date of Manufacturing
- Date of Expiry
- Manufacturer Name and registered address
- Manufacturer License number
- Storage conditions
- Number of Tablets / strips contained in the box
- Place of manufacture (Made in\_\_\_\_\_)

### **5-Ply Shipper Package:**

Each 5 Ply Shipper shall contain 4 Millboard / Greyboard boxes. The boxes shall be packed in a weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

Each shipping carton when packed should weigh not more than 50 kg.

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Place of manufacture (Made in\_\_\_\_\_)

## **H. Labelling:**

### **General requirements of the labels:**

- Shall meet WHO GMP standards.
- All labels should be peel proof
- "RNTCP- **Central Government Supply- NOT FOR SALE**" to be imprinted on the labels of Millboard / Greyboard and & 5 Ply Shippers.

**Labelling on Millboard/Greyboard Box:**

The label shall indicate the content of Bedaquiline in each tablet.

The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry and storage requirements along with the number strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

**MILLBOARD/GREYBOARD BOX**

<b>MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 52 BEDAQUILINE TABLETS 100 mg (25 HDPE Bottles)</b>	
<b>Each HDPE Bottle contains 188 tablets of Bedaquiline-100mg</b>	
<b>Batch No.:</b>	
<b>Mfg. Date:</b>	
<b>Exp. Date:</b>	
<b>“RNTCP – Central Government Supply – Not for Sale”</b>	
<b>Manufacturer’s Name &amp; Address</b>	
<b>Manufacturing Lic. No.</b>	

### Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug.

The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

### 5 – PLY SHIPPER

<p><b>MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 52</b> <b>BEDAQUILINE 100MG</b> <b>42 Millboard / Greyboard Boxes x 25 HDPE Bottles</b></p>
<p><b>Each HDPE Bottle contains 188 tablets of Bedaquiline-100mg</b></p>
<p><b>Batch No.:</b></p>
<p><b>Mfg. Date:</b></p>
<p><b>Exp. Date:</b></p>
<p><b>“RNTCP – Central Government Supply – Not for Sale”</b></p>
<p><b>Manufacturer’s Name &amp; Address</b></p>
<p><b>Manufacturing Lic. No.</b></p>

### I. Colour Coding:

The labels on Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

## **J. Bar Coding**

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

- 1) Product Name/content
- 2) Product Strength
- 3) Batch Number
- 4) Date of Manufacturing
- 5) Date of Expiry
- 6) Manufacturer Address
- 7) Manufacturer License number
- 8) Storage conditions requirement
- 9) Number of HDPE Bottles in a Millboard/Greyboard Boxes and 5 Ply Shipper

## **K. Markings**

All packaging units and invoices must bear the name of the product, product strength, manufacturing and expiry date, storage conditions, manufacturer address and license number.

## **L. Documentation**

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the product being supplied.