




<b>Metronidazole</b>			
<b>No. : RPB 207</b>	<b>Rev : 03</b>	<b>Eff. date : 18 05 18</b>	<b>Sign : </b>

- 1 **Quality**
  - 1.1 USP 37, 2014
- 2 **Additional Requirements**
  - 2.1 Bulk Density : 0,50 – 0,65 gr/ml
  - 2.2 Tapping Density : 0,70 – 0,85 gr/ml
  - 2.3 Arrival Date : NMT. 12 months from manufacturing date
- 3 **Certificate of Analysis from Manufacturer**

To be stated on the certificate

  - 3.1 Manufacturer name and address
  - 3.2 Product name , batch/lot number
  - 3.3 Results of test and assays
  - 3.4 Compliance with USP 37 and additional requirements
  - 3.5 Quality designation
  - 3.6 Date of manufacturing, expiration (year-month) and date of released (year- month-day)
  - 3.7 Approval/signature of QA/QC responsibility
- 4 **Attached update Good Manufacture Practice Certificate**
- 5 **Package**

Cardboard drum @ 25 kg, with original seal (inside and outside) from manufacture.  
Tobe staed on goods, label original from manufacture at primary and secondary package each  
Preserve in well-closed and light resistant containers.
- 6 **Labeling**

To be stated on goods **label original from manufacturer**, packing list and invoice :

  - 6.1 Name of manufacturer and address
  - 6.2 Product name, batch/lot number, manufacturing and expiration date
  - 6.3 Quality designation
  - 6.4 Gross/net weight
  - 6.5 Number of packages
- 7 **Reference Documents**
  - 7.1 USP 37, 2014
- 8 **History**

Purchasing specification is revision of RPB 207 revision 02 with change in deleting the review point.

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**9 Distribution**

In general, a copy of this specification is distributed to :

- 9.1 Procurement Dept.
- 9.2 Quality Control Dept.

**10 Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	<i>[Signature]</i>	18 05 18
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	18 05 18
Approved by	Quality Control Manager	AM	<i>[Signature]</i>	18 05 18
	Research & Development Manager	LB	<i>[Signature]</i>	18 05 18
	Quality Assurance Manager	PM	<i>[Signature]</i>	18 05 18