


Metformin Hydrochloride (Metformin Hidrokloride)			
No. : RPB 283	Rev : 04	Eff. date : 170426	Sign : 

- 1 **Quality** : USP 37, 2014
- 2 **Additional Requirements**
 - 2.1 **Arrival Date** : Max. 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
 - 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, double plastic PE, with original seal (inside and outside) from manufacture.
To be stated on goods, label original from manufacture at primary and secondary package each.
Preserve in well – closed 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**
USP 37, 2014
- 8 **History**
Purchasing Specification is revision of RPB 283 revision 03 with change in the format document
- 9 **Review**
This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager.

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10 Distribution

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

- 10.1 Procurement Dept.
- 10.2 Quality Control Dept.

11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	<i>[Signature]</i>	17 04 26
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	17 04 26
Approved by	Quality Control Manager	AM	<i>[Signature]</i>	17 04 26
	Research & Development Manager	LB	<i>[Signature]</i>	17 04 26
	Quality Assurance Manager	PM	<i>[Signature]</i>	17 04 26

12 Review

No.	Position	Date	Signature	Recommendation
1.	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2.	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			