

Levofloxacin Hemihydrate			
No. : RPB 290	Rev : 08	Eff. date : 171128	Sign : J

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**

Vat @ 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 tight 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**

USP 37, 2014

8 **History**

Purchasing specification is revision of RPB 290 revision 07 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

10 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		171128
Checked by	Analytical Method Assistant Manager	LB		171128
Approved by	Quality Control Manager	AM	^{an}	171128
	Research & Development Manager	LB		171128
	Quality Assurance Manager	PM		171128

11 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			