


Gentamicin Sulfate (Gentamicin Sulfate)			
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- 1 **Quality** : USP 39, 2016

- 2 **Additional Requirements**
 - Bioburden : NMT 100 cfu
 - Arrival Date : Max. 6 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 39 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 Practise Certificate**

- 5 **Package**

Tin aluminium @ 8 kg, 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.

- 5 **Labeling**

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

 - 5.1 Name of manufacturer and address
 - 5.2 Product name, batch/lot number, manufacturing and expiration date
 - 5.3 Quality designation
 - 5.4 Gross/net weight
 - 5.5 Number of packages

- 6 **Reference Documents**

USP 39, 2016


- 7 **History**

Purchasing specification is revision of RPB 521 revision 04 with change in the quality of USP 36 to USP 39 and the format document.

- 8 **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.







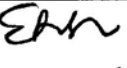
Gentamicin Sulfate (Gentamicin Sulfate)			
No. : RPB 139	Rev : 05	Eff. date : 17 08 09	Sign : 

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		17 08 08
Checked by	Analytical Method Assistant Manager	LB		17 08 08
Approved by	Quality Control Manager	AM	^{an-} 	17 08 08
	Research & Development Manager	LB		17 08 09
	Quality Assurance Manager	PM		17 08 09

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			