


Ceftriaxone Sodium, Sterile			
No. : RPB 022	Rev : 16	Eff. date : 170103	Sign : 

1 Quality

- 1.1 USP 39, 2016
- 1.2 Internal specification

2 Additional Requirements

- 2.1 Absorbance : λ 430 nm NMT.0.200
 λ 450 nm NMT.0.125
 λ 600 nm NMT.0.009
- 2.2 Bulk density : 0,40-0,55 g/ml
- 2.3 Tapping density : 0,55-0,65 g/ml
- 2.4 Assay : 850-900 μ g/mg (as Ceftriaxone anhydrate)
- 2.5 Arrival date : NMT. 6 months from manufacturing date
- 2.6 Uniform quality throughout lots/batches

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 quality 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 container @ 10 kg, with original seal (inside and outside) from manufacture, the carton box with little sample outside (\pm 40g, sterile condition) for test every batch.

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

- 7.1 USP 39, 2016
- 7.2 Internal specification

Ceftriaxone Sodium, Sterile			
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8 History

Purchasing specification is revision of RPB 022 revision 15 with change in the quality and 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

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		161230
Checked by	Analytical Method Assistant Manager	LB		161230
Approved by	Quality Control Manager	AM		161230
	Research & Development Manager	LB		161230
	Quality Assurance Manager	PM		170103

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			