| 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 | µg/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 (±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 | | | |