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|--------------------------------------|-----------------|-----------------------------|---|
| <b>Spiramycin<br/>( Spiramicin )</b> |                 |                             |   |
| <b>No. : RPB 243</b>                 | <b>Rev : 03</b> | <b>Eff. date : 18 07 10</b> | <b>Sign : </b> |

1 **Quality** : EP 2008

2 **Additional Requirements**

- 2.1 Potency : NLT. 4100 UI/mg
- 2.2 Arrival Date : NMT. 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 EP 2008 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 **Package**

Cardboard drum @10 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**

EP 2008

7 **History**

Purchasing specification is revision of RPB 243 revision 02 with change in deleting the review point..

8 **Distribution**

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

- 8.1 Procurement Dept.
- 8.2 Quality Control Dept.



|                                      |                 |                             |                                  |
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**9 Approval**

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