Spiramycin (Spiramicin)			
No. : RPB 243	**Rev : 03**	**Eff. date :** 18 07 10	**Sign :**

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