INDOFARMA

PURCHASING SPECIFICATION

Polymyxin B Sulfate,*Superfine*			
No. : RPB 159	**Rev : 01**	**Eff. date :** 180518	**Sign :**

1 **Quality** : Farmakope Indonesia Edition V, 2014

2 **Additional Requirements**

2.1 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 Farmakope Indoensia Edition V, 2014
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 Practice Certificate**

5 **Package**

Vat @ 25 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

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 Farmakope Indonesia Edition V, 2014

8 **History**

Purchasing specification is revision of RPB 159 revision 00 with change in the quality, format document, and deleting the review point.

9 **Distribution**

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

9.1 Procurement Dept.
9.2 Quality Control Dept

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10 **Approval**

Preparation steps	**Position**	**Code**	**Signature**	**Date**
Prepared by	Starting and Packaging Material Testing Assistant Manager	**AM**		180518
Checked by	Analytical Method Assistant Manager	**LB**		180518
Approved by	Quality Control Manager	**AM**		180518
	Research & Development Manager	**LB**		180518
	Quality Assurance Manager	**PM**		180518