

Bacitracin Zinc			
No. : RPB 148	Rev : 01	Eff. Date : 18 05 18	Sign : B

1 Quality

- 1.1 Farmakope Indonesia Edition V, 2014
- 1.2 USP 39, 2016

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 Quality
- 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 Carton @ 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
- 7.2 USP 39, 2016

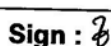
8 History

Purchasing specification is revision of RPB 148 revision 00 with change in the quality, format document, and deleting the review point.

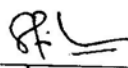

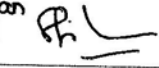
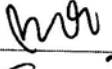
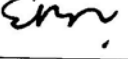
9 Distribution

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

- 9.1 Procurement Dept.
- 9.2 Quality Control Dept

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No. : RPB 148	Rev : 01	Eff. Date : 180518	Sign : 

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	^{as} 	180518
	Research & Development Manager	LB		180518
	Quality Assurance Manager	PM		180518