


Thiamphenicol		
No. : RPB 153	Rev : 08	Eff. date : 180425 Sign : 

1 Quality

- 1.1 Farmakope Indonesia Edition V, 2014
- 1.2 Inhouse Indofarma

2 Additional Requirements

- 2.1 Bulk Density : 0.56 - 0.66 gr/ml
- 2.2 Tapped Density : 0.80 - 0.88 gr/ml
- 2.3 Arrival date : NMT. 12 months from manufacturing date
- 2.4 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 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 Indonesia Pharmacopeia V, 2014
- 7.2 Inhouse Indofarma

8 History

Purchasing specification is revision of RPB 153 revision 07 with change in the quality of Farmakope Indonesia IV, 1995 and BP 2013 to Farmakope Indonesia V, 2014 and Inhouse Indofarma, and deleting the review point.

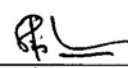

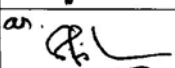

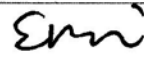
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9 Distribution

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

- 9.1 Procurement Dept.
- 9.2 Quality Control Dept

10 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		180425
Checked by	Analytical Method Assistant Manager	LB		180425
Approved by	Quality Control Manager	AM	^{an} 	180425
	Research & Development Manager	LB		180425
	Quality Assurance Manager	PM		180425