

Amitriptyline Hydrochloride			
No. : RPB 218	Rev : 02	Eff. date : 18 02 13	Sign : <i>ab</i>

1 Quality

- 1.1 Farmakope Indonesia Edition V, 2014
- 1.2 USP 37, 2014

2 Additional Requirements

- 2.1 Arrival Date : NMT. 12 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 Practise Certificate

5 Package

Cardboard drum @ 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 tight 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, 2014
- 7.2 USP 37

8 History

Purchasing specification is revision of RPB 218 revision 01 with change in the format document.

9 Review

This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager.



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10 Distribution

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

- 10.1 Procurement Dept.
- 10.2 Quality Control Dept.

11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	<i>[Signature]</i>	18 02 13
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	18 02 13
Approved by	Quality Control Manager	AM	<i>[Signature]</i>	18 02 13
	Research & Development Manager	LB	<i>[Signature]</i>	18 02 13
	Quality Assurance Manager	PM	<i>[Signature]</i>	18 02 13

12 Review

No.	Position	Date	Signature	Recommendation
1	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			