


Ethambutol Hydrochloride			
No. : RPB 156	Rev : 02	Eff. date 17 12 05	Sign : 

1 Quality

- 1.1 Farmakope Indonesia V, 2014
- 1.2 USP 37, 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 Indonesia V and USP 37
- 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 V, 2014
- 7.2 USP 37, 2014

8 History

This specification is revision of RPB 156 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.

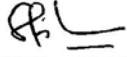

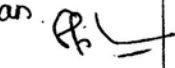

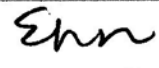
10 Distribution

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

- 10.1 Procurement Dept.
- 10.2 Quality Control Dept

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11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		171205
Checked by	Analytical Method Assistant Manager	LB		171205
Approved by	Quality Control Manager	AM	an. 	171205
	Research & Development Manager	LB		171205
	Quality Assurance Manager	PM		171205

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			