

Pyrazinamide		
No. : RPB 158	Rev : 09	Eff. date : 18 04 25 Sign : <i>8</i>

1 Quality

- 1.1 Farmakope Indonesia 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 Practise Certificate

5 Package

Vat Carton @ 25 kg, double plastic PE 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 39, 2016

8 History

Purchasing specification revision of RPB 158 revision 08 with change in the quality of USP 35, 2015 to Farmakope Indonesia V, 2014 and USP 39, 2016 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	<i>P.L.</i>	180425
Checked by	Analytical Method Assistant Manager	LB	<i>LB</i>	180425
Approved by	Quality Control Manager	AM	<i>an. P.L.</i>	180425
	Research & Development Manager	LB	<i>[Signature]</i>	180425
	Quality Assurance Manager	PM	<i>[Signature]</i>	180425