


Albendazole (For Suspension)			
No. : RPB 170 a	Rev : 02	Eff. date : 18 06 07	Sign : 

1 Quality

- 1.1 Farmakope Indonesia V, 2014
- 1.2 USP 37, 2014
- 1.3 Inhouse Indofarma

2 Additional Requirements

- 2.1 Tapping Density : 0,32 – 0,34 g/ml
- 2.2 Bulk Density : 0,23 – 0,25 g/ml
- 2.3 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 and Additional Requirements
- 3.5 Date of manufacturing, expiration (year-month) and date of released (year- month-day)
- 3.6 Approval/signature of QA/QC responsibility

4 Package

Cardboard drum @ 25 kg, with original seal (inside and outside) from manufacture.
To be goods, label original from manufacture at primary and secondary package each.
Preserve in tight containers.

5 Labeling

To be stated on goods **label original from manufacturer**, packing list and invoice :

- 5.1 Name of manufacturer and address
- 5.2 Product name, batch/lot number, manufacturing and expiration date
- 5.3 Quality designation
- 5.4 Gross/net weight
- 5.5 Number of packages

6 Reference Documents

- 6.1 Farmakope Indonesia V, 2014
- 6.2 USP 37, 2014
- 6.3 Inhouse Indofarma

7 History

Purchasing specification is revision of RPB 170a revision 01 with change in the format document and deleting the review point.

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8 Distribution

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

- 8.1 Procurement Dept.
- 8.2 Quality Control Dept.

9 Approval

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