

**Pseudoephedrine Hydrochloride
(Pseudoefedrin Hidroklorida)**

No. : RPB 163	Rev : 02	Eff. date : 18 07 10	Sign : d.
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1 Quality

- 1.1 Farmakope Indonesia 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 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 and light resistant container.

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

7 History

Purchasing specification is revision of RPB 163 revision 01 with change in the quality and deleting the review point.

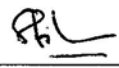

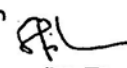
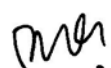
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8 Distribution

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		
Checked by	Analytical Method Assistant Manager	LB		
Approved by	Quality Control Manager	AM	^{an} 	
	Research & Development Manager	LB		
	Quality Assurance Manager	PM	