


<b>Reserpine</b>			
<b>No. : RPB 198</b>	<b>Rev : 02</b>	<b>Eff. date : 18 05 24</b>	<b>Sign : </b>

**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 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**

Cardboard drum @ 10 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 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**

Purchasing specification is revision of RPB 198 revision 01 with change in the format document and deleting the review point.



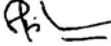

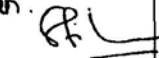

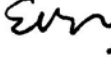
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**9 Distribution**

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

- 9.1 Procurement Dept.
- 9.2 Quality Control Dept.

**10 Approval**

<b>Preparation steps</b>	<b>Position</b>	<b>Code</b>	<b>Signature</b>	<b>Date</b>
Prepared by	Starting and Packaging Material Testing Assistant Manager	<b>AM</b>		180524
Checked by	Analytical Method Assistant Manager	<b>LB</b>		180524
Approved by	Quality Control Manager	<b>AM</b>	<sup>an.</sup> 	180524
	Research & Development Manager	<b>LB</b>		180524
	Quality Assurance Manager	<b>PM</b>		180524