




<b>Phenobarbital, Microfine ( Fenobarbital, Microfine )</b>			
<b>No. : RPB 229</b>	<b>Rev : 04</b>	<b>Eff. date : 17 11 28</b>	<b>Sign : </b>

**1 Quality**

- 1.1 Farmakope Indonesia Edisi V, 2014
- 1.2 USP 37, 2014
- 1.3 BP 2013

**2 Additional Requirements**

- 2.1 Particle size :  $\leq 45 \mu\text{m}$  Min. 90,0%
- 2.2 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 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 edisi V, 2014
- 7.2 USP 37, 2014
- 7.3 BP 2013

**8 History**

Purchasing specification revision of RPB 229 revision 03 with change in the format document

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<b>No. : RPB 229</b>	<b>Rev : 04</b>	<b>Eff. date : 171128</b>	<b>Sign : [Signature]</b>

**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

**11 Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	[Signature]	171128
Checked by	Analytical Method Assistant Manager	LB	[Signature]	171128
Approved by	Quality Control Manager	AM	[Signature]	171128
	Research & Development Manager	LB	[Signature]	171128
	Quality Assurance Manager	PM	[Signature]	171128

**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			