



PURCHASING SPECIFICATION

Aminophylline (Aminofillin)			
No. : RPB 231	Rev : 02	Eff. date : 18 05 18	Sign : <i>B</i>

- 1 **Quality**
 - 1.1 Farmakope Indonesia V, 2014
 - 1.2 USP 37, 2014

- 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 Practice Certificate**

- 5 **Package**

Cardboard Drum @1 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 tight 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 231 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

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	<i>[Signature]</i>	180518
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	180518
Approved by	Quality Control Manager	AM	an. <i>[Signature]</i>	180518
	Research & Development Manager	LB	<i>[Signature]</i>	180518
	Quality Assurance Manager	PM	<i>[Signature]</i>	180518