

**Simethicone  
( Simetikon 100 % )**

No. : RPB 242	Rev : 03	Eff. date : 18 05 18	Sign :
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- 1 **Quality**
  - 1.1 USP 37, 2014
  - 1.2 Farmakope Indonesia V, 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 **Attached update Good Manufacture Practice Certificate**
- 5 **Package**

Carton box @18kg with inner package plastic bag, 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 USP 37, 2014
  - 7.2 Farmakope Indonesia V, 2014
- 8 **History**

Purchasing specification is revision of RPB 242 revision 02 with change in the quality and deleting the review point.



PURCHASING SPECIFICATION

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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	<i>[Signature]</i>	180518
	Research & Development Manager	LB	<i>[Signature]</i>	180518
	Quality Assurance Manager	PM	<i>[Signature]</i>	180518