

PURCHASING SPECIFICATION

Acetaminophen (Parasetamol)

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No	•	RP	B16	36			
Revisi	:	02					
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1 Quality

1.1 Farmakope Indonesia V, 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 Package

Cardboard drum @ 25 kg, double plastic PE,with original seal (inside and outside) from manufacture.

To be stated on goods, original label from manufacture at both of primary and secondary package Preserve in well - closed containers.

5 Labeling

To be stated on goods original label 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

7 History

Revision Eff. Date		Change			
02		Change in the document format			
	12 DEC 2018	Change in the reference document from Farmakope Indonesia V 2014 and BP 2013 to Farmakope Indonesia edition V, 2014			
		3. Deleting the review point			



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No	: RPB166
Revisi	: 02

Berlaku: 12 DEC 2018
Paraf: 1.

8 Distribution

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	RL	12 Des 2018
Checked by	Analytical Method Assistant Manager	LB	7	12 Des 2018
	Quality Control Manager	AM	an Pil	12 Des 2018
Approved by	Research & Development Manager	LB	ans	12 Des 2018
	Quality Assurance Manager	PM	Erri	12 Des 2018