

### **PURCHASING SPECIFICATION**

**Antalgin** 

(Dipyrone/Methampyrone/Metamizole Sodium)

No : RPB219

Revisi: 07

Berlaku : 29 NOV 20

Paraf :

1 Quality

: 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 BP-2013
- 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

Farmakope Indonesia V, 2014

#### 7 History

Revision Eff. Date		Change	
07	29 NOV 2018	Change in the document format	
		2. Change in the reference document from BP 2013 to Farmakope Indonesia V, 2014	
		3. Deleting the review point	

#### 8 Distribution

A copy of this specification is distributed to:

- 8.1 Procurement Dept.
- 8.2 Quality Control Dept



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# 9 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM	RIL	29 NOV 2018
Checked by	by Analytical Method Assistant Manager		J.	29 NOV 2018
	Quality Control Manager	AM	an Ri	29 NOV 2018
Approved by	Research & Development Manager	LB	W.	29 1004 2018
	Quality Assurance Manager	PM	Evi	29 NOV 2018