
	PURCHASING SPECIFICATION Antalgin (Dipyrone/Methampyrone/Metamizole Sodium)	No : RPB219
		Revisi : 07
		Berlaku : 29 NOV 2018
		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	1. 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	<i>[Signature]</i>	29 NOV 2018
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	29 NOV 2018
Approved by	Quality Control Manager	AM	^{an} <i>[Signature]</i>	29 NOV 2018
	Research & Development Manager	LB	<i>[Signature]</i>	29 NOV 2018
	Quality Assurance Manager	PM	<i>[Signature]</i>	29 NOV 2018