

 indofarma	PURCHASING SPECIFICATION Furosemide (Furosemida)	No : RPB212
		Revisi : 05
		Berlaku : 16 OCT 2018
		Paraf : <i>[Signature]</i>

1 Quality

- 1.1 Farmakope Indonesia Edition V, 2014
- 1.2 USP 39, 2016
- 1.3 Inhouse Indofarma

2 Additional Requirements

- 2.1 Particle size < 10 µm : NLT. 90,0 %
- 2.2 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 and Additional Requirements
- 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, 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 , light-resistant 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 Edition V, 2014
- 6.2 USP 39, 2016
- 6.3 Inhouse Indofarma

7 History

Revision	Eff. Date	Change
05	16 OCT 2018	1. Change into new logo 2. Change in the header format 3. Change in reference document from USP 37 2014 and BP 2013 to USP 39 and Inhouse Indofarma

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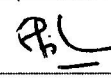
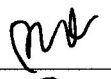
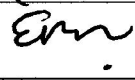
8 Distribution

A copy of this purchasing 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		16 Okt 2018
Checked by	Analytical Method Assistant Manager	LB		16 Okt 2018
Approved by	Quality Control Manager	AM	as 	16 Okt 2018
	Research & Development Manager	LB		16 Okt 2018
	Quality Assurance Manager	PM		16 Okt 2018