indofarma	PURCHASING SPECIFICATION Furosemide (Furosemida)	No : RPB212 Revisi : 05 Berlaku : 16 OCT 2018 Paraf :

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**	a/n	16 Okt 2018
	Research & Development Manager	**LB**		16 Okt 2018
	Quality Assurance Manager	**PM**		16 Okt 2018