 indofarma	PURCHASING SPECIFICATION Magnesium Sulfate	No : RPB227
		Revisi : 05
		Berlaku : 29 NOV 2018
		Paraf : ↓

1 Quality

- 1.1 USP 39, 2016
- 1.2 Farmakope Indonesia Edition 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 @ 20 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 each. 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 USP 39, 2016
- 6.2 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 USP 36, 2013 to USP 39, 2016 and Farmakope Indonesia V, 2014 3. Deleting the review point

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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	<i>APL</i>	29 NOV 2018
Checked by	Analytical Method Assistant Manager	LB	<i>LB</i>	29 NOV 2018
Approved by	Quality Control Manager	AM	<i>APL</i>	29 NOV 2018
	Research & Development Manager	LB	<i>Mh</i>	29 NOV 2018
	Quality Assurance Manager	PM	<i>Sum</i>	29 NOV 2018