
 <b>indofarma</b>	<b>PURCHASING SPECIFICATION</b> Dried Aluminium Hydroxide Gel, Heavy	No : RPB235
		Revisi : 09
		Bertaku : <b>12 DEC 2018</b>
		Paraf : 

**1 Quality**

- 1.1 Farmakope Indonesia edition V, 2014
- 1.2 USP 37, 2014
- 1.3 Inhouse Indofarma

**2 Additional Requirements**

- 2.1 Bulk Density : 0,28 – 0,50 g/ml
- 2.2 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 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 @ 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.  
Preserve in tight 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 37, 2014
- 6.3 Inhouse Indofarma

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### 7 History

Revision	Eff. Date	Change
09	<b>12 DEC 2018</b>	1. Change in the document format 2. Change in the reference document from USP 36 to Farmakope Indonesia edition V 2014, USP 37, and Inhouse Indofarma 3. Deleting the review point

### 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>[Signature]</i>	12 Des 2018
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	12 Des 2018
Approved by	Quality Control Manager	AM	<i>[Signature]</i>	12 Des 2018
	Research & Development Manager	LB	<i>[Signature]</i>	12 Des 2018
	Quality Assurance Manager	PM	<i>[Signature]</i>	12 Des 2018