
	PURCHASING SPECIFICATION Dried Aluminium Hydroxide Gel, Light	No : RPB259
		Revisi : 01
		Berlaku : 12 DEC 2018
		Paraf : 

7 History

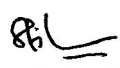



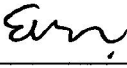
Revision	Eff. Date	Change
00 01	12 DEC 2018	1. Change in the document format 2. Change in the reference document from USP 36 to Farmakope Indonesia edition V 2014, USP 37, and Inhouse Indofarma 3. Deleting the review point


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		
Checked by	Analytical Method Assistant Manager	LB		
Approved by	Quality Control Manager	AM	an. 	
	Research & Development Manager	LB		
	Quality Assurance Manager	PM		

 indofarma	PURCHASING SPECIFICATION Empty Gelatine Capsule No. 0 for Cefadroxil 500 mg	No : RPB475
		Revisi : 08
		Berlaku : 12 DEC 2018
		Paraf : <i>A</i>

1 Quality

- 1.1 USP 39, 2016
- 1.2 Multistate File, Capsugel, 3th edition, 1998
- 1.3 Inhouse Indofarma

2 Additional Requirements

- 2.1 Marking Of Capsule : Black color CFD 500 and INF on cap and body
 - Color Of Capsule :
 - Cap : Orange Op
 - Body : Orange Op
- 2.2 Uniformity of weight : 89,0 - 107,0 mg
- 2.3 Uniformity of measure
 - Body length : 17,98 - 18,90 mm
 - Length cap : 10,26 - 11,18 mm
 - Diameter of body : 7,28 - 7,40 mm
 - Diameter of cap : 7,58 - 7,70 mm
 - Total length of body : 21,4 - 22,0 mm
- 2.4 Microbial Limit Test
 - Total microbial aerobic numbers : NMT. 1000 kol/g
 - Yeast & mould numbers : NMT. 100 kol/g
 - Escherichia coli : Negative
 - Salmonella : Negative
 - Pseudomonas aeruginosa : Negative
 - Staphylococcus aureus : Negative
- 2.5 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

Corrugated box @ 100.000 pcs, 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 tight, light-resistant containers.