

Diluted Isosorbide Dinitrate (25%) (Isosorbid Dinitrat, encer 25%)			
No. : RPB 197	Rev : 01	Eff. date : 18 07 10	Sign : A.

1 Quality

- 1.1 USP 39, 2016
- 1.2 Farmakope Indonesia V, 2014

2 Additional Requirements

- 2.1 Assay : 95,0 – 105,0 %
- 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 @ 25 kg, with original seal (inside and outside) from manufacture.

To be stated on goods, label original from manufacture at primary and secondary package each. Preserve in well-closed containers.

5 Labeling

To be stated on goods **label original 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

This specification is revision of RPB 197 revision 00 with change in the quality, format document, and deleting the review point.



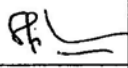

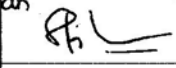
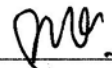
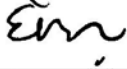
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8 Distribution

In general, 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		180710
Checked by	Analytical Method Assistant Manager	LB		180710
Approved by	Quality Control Manager	AM	^{an} 	180710
	Research & Development Manager	LB		180710
	Quality Assurance Manager	PM		180710