


Glyburide (Glibenklamida)			
No. : RPB 177	Rev : 08	Eff. date : 17 11 28	Sign : 

1 Quality

- 1.1 USP 37, 2014
- 1.2 Inhouse Indofarma

2 Additional Requirements

- 2.1 Particle size : $\leq 10 \mu\text{m}$ Min. 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
- 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 Attached update Good Manufacture Practice Certificate

5 Package

Vat @ 25 kg, plastic PE, with original seal (inside and outside) from manufacture.
To be stated on goods, label original from manufacture at primary
Preserve in tight containers.

6 Labeling

To be stated on goods **label original from manufacturer**, packing list and invoice :


- 6.1 Name of manufacturer and address
- 6.2 Product name, batch/lot number, manufacturing and expiration date
- 6.3 Quality designation
- 6.4 Gross/net weight
- 6.5 Number of packages

7 Reference Documents

- 7.1 USP 37, 2014
- 7.2 Inhouse Indofarma

8 History

Purchasing specification is revision of RPB 177 revision 07 with change in the format document

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9 Review



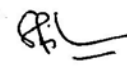
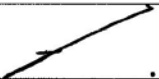
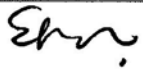
This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality assurance Manager.

10 Distribution

In general, a copy of this specification is distributed to :

- 10.1 Procurement Dept.
- 10.2 Quality Control Dept

10 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		171128
Checked by	Analytical Method Assistant Manager	LB		171128
Approved by	Quality Control Manager	AM	^{an} 	171128
	Research & Development Manager	LB		171128
	Quality Assurance Manager	PM		171128

11 Review

No.	Position	Date	Signature	Recommendation
1	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			