Glyburide (Glibenklamida)			
No. : RPB 177	**Rev : 08**	**Eff. date : 171128**	**Sign :**

1 **Quality**

1.1 USP 37, 2014

1.2 Inhouse Indofarma

2 **Additional Requirements**

2.1 Particle size : ≤ 10 µm 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, Researche & 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**		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			