


Chlorpropamide, Microfine			
No. : RPB 188	Rev : 02	Eff. date : 18 02 13	Sign : 

1 Quality

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

2 Additional Requirements

- 2.1 Particle Size : Microfine $\leq 45 \mu\text{m}$ NLT. 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 Practise Certificate**5 Package**

Cardboard drum @ 25 kg, with original seal (inside and outside) from manufacture.
Tobe stated on goods, label original from manufacture at primary and secondary package each. Preserve in well-closed 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 Farmakope Indonesia Edition V, 2014
- 7.2 USP 37, 2014
- 7.3 Inhouse Indofarma

8 History

Purchasing specification is revision of RPB 188 is revision 01 with change in the format document.

Chlorpropamide, Microfine			
No. : RPB 188	Rev : 02	Eff. date : 180213	Sign : 4

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.

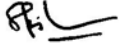

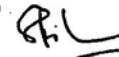
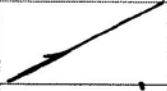

10 Distribution

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

10.1 Procurement Dept.

10.2 Quality Control Dept.

11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		180213
Checked by	Analytical Method Assistant Manager	LB		180213
Approved by	Quality Control Manager	AM	^{an} 	180213
	Research & Development Manager	LB		180213
	Quality Assurance Manager	PM		180213

12 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			