



PURCHASING SPECIFICATION

Irbesartan			
No. : RPB 292	Rev : 01	Eff. date : 18 03 23	Sign :

- 1 **Quality**
 - 1.1 USP 39, 2016
 - 1.2 Farmakope Indonesia V, 2014

- 2 **Additional Requirements**
 - 2.1 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
 - 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, double plastic PE, 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 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 39, 2016
 - 7.2 Farmakope Indonesia V, 2014

- 8 **History**

This purchasing specification is revision of RPB 292 revision 00 with change in the quality and format document.

- 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.

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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	<i>[Signature]</i>	180323
Checked by	Analytical Method Assistant Manager	LB	<i>[Signature]</i>	180323
Approved by	Quality Control Manager	AM	<i>[Signature]</i>	180323
	Research & Development Manager	LB	<i>[Signature]</i>	180323
	Quality Assurance Manager	PM	<i>[Signature]</i>	180323

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			