

Ketoconazole (Ketokonazol)			
No. : RPB 260	Rev : 01	Eff. date : 17 09 26	Sign : Ø

- 1 **Quality** : 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 Farmakope Indonesia V, 2014
 - 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 @ 25kg 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 well-closed containers.
- 6 **Labelling**
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**
Farmakope Indonesia V, 2014
- 8 **History**
This specification is revision of RPB 260 revision 00 with change in the quality and the 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.
- 10 **Distribution**
In general, a copy of this specification is distributed to :
 - 10.1 Procurement Dept.
 - 10.2 Quality Control Dept.



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11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		17 09 26
Checked by	Analytical Method Assistant Manager	LB		17 09 26
Approved by	Quality Control Manager	AM	^{an.}	17 09 26
	Research & Development Manager	LB		17 09 26
	Quality Assurance Manager	PM		17 09 26

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			