


Lidocaine hydrochloride (Lidokain Hidroklorida)			
No. : RPB 228	Rev : 07	Eff. date : 18 07 13	Sign : 

- 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 **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 well-closed containers.

- 5 **Labeling**

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

 - 5.1 Name of manufacturer and address
 - 5.2 Product name, batch/lot number, manufacturing and expiration date
 - 5.3 Quality designation
 - 5.4 Gross/net weight
 - 5.5 Number of packages

- 6 **Reference Documents**

Farmakope Indonesia V, 2014

- 7 **History**

Purchasing specification is revision of RPB 228 revision 06 with change in the quality of USP 36 to Farmakope Indonesia V, format document and deleting the review point.

- 8 **Distribution**

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

 - 8.1 Procurement Dept.
 - 8.2 Quality Control Dept.



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9 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		18 07 13
Checked by	Analytical Method Assistant Manager	LB		18 07 13
Approved by	Quality Control Manager	AM	^{an}	18 07 13
	Research & Development Manager	LB		18 07 13
	Quality Assurance Manager	PM		18 07 13