



Metoclopramide hydrochloride (Metoklopramida Hidroklorida)			
No. : RPB 272	Rev : 06	Eff. date : 17 03 02	Sign : 8

- 1 Quality** : USP 36, 2013
- 2 Additional Requirements**
 - 2.1 Arrival Date : Max. 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 USP 36
 - 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**

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, light-resistant 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**

USP 36, 2013
- 8 History**

Purchasing specification is revision and substitute of RPB 272 revision 05 with change in format document.
- 9 Review**

This specification will be reviewed every 2 years or less (if necessary) by The Research & Development Manager, Quality Control Manager, and Quality Assurance Manager



PURCHASING SPECIFICATION

Metoclopramide hydrochloride (Metoklopramida Hidroklorida)			
No. : RPB 272	Rev : 06	Eff. date : 170302	Sign :

10 Distribution

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

10.1 Procurement Dept.

11 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		170302
Checked by	Analytical Method Assistant Manager	LB		170302
Approved by	Quality Control Manager	AM	^{an}	170302
	Research & Development Manager	LB		170302
	Quality Assurance Manager	PM		170302

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			