
	PURCHASING SPECIFICATION Ketorolac Tromethamol (Ketorolac Tromethamine)	No : RPB291
		Revisi : 01
		Berlaku : 06 AUG 2018
		Paraf : 

1 **Quality** : USP 39, 2016

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 USP 39
- 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 @ 5 kg, with original seal (inside and outside) from manufacture.

To be stated on goods, original label from manufacture at both of primary and secondary package.

Preserve in tight, light resistant 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**

USP 39, 2016

7 **History**

Revision	Eff. Date	Change
00	28 MAR 2013 ²⁰¹² 28 MAR 2013	The first publication
01	06 AUG 2018	1. Change into new logo 2. Change in the header format 3. Change of reference from USP 34 to USP 39 4. Change in deleting the review point 5. Change in the document format and field code



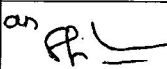

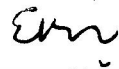
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8 Distribution

A copy of this purchasing specification is distributed to :

- 8.1 Procurement Dept.
- 8.2 Quality Control Dept.

9 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		06 Agu 2018
Checked by	Analytical Method Assistant Manager	LB		06 Agu 2018
Approved by	Quality Control Manager	AM	^{an} 	06 Agu 2018
	Research & Development Manager	LB		06 Agu 2018
	Quality Assurance Manager	PM		06 Agu 2018