

PURCHASING SPECIFICATION

Page1of 2

Trihexyphenidyl Hydrochloride (Triheksifenidil Hidrokloride)

No.: RPB 220 Rev: 00 Eff. date: 180323 Sign: 8

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 Attached update Good Manufacturing Practise Certificate

5 Package

Vat Carton @ 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.

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 39, 2016

8 History

Purchasing specification is the first publication

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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Page2of 2

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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	8-	186323
Checked by	Analytical Method Assistant Manager	LB		180323
Approved by	Quality Control Manager	AM	on R	180323
	Research & Development Manager	LB		180323
	Quality Assurance Manager	PM	Ehn	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	,		