Digoxin (Digoksin)			
No. : RPB 191	Rev : 09	Eff. date : 170426	Sign :

1 **Quality**

1.1 USP 37, 2014

1.2 Internal specification

2 **Additional Requirements**

2.1 Particle Size : ≤ 10 µm Min. 90 %

2.2 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 quality and additional requirements

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 primiary 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**

6.1 USP 37, 2014

6.2 Internal specification

8 **History**

Purchasing specification is revision of RPB 191 revision 08 with change in the format document.

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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.

11 **Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		170426
Checked by	Analytical Method Assistant Manager	LB		170426
Approved by	Quality Control Manager	AM		170426
	Research & Development Manager	LB		170426
	Quality Assurance Manager	PM		170426

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			