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|-------------------------------|-----------------|---------------------------|-----------------|
| <b>Digoxin<br/>(Digoksin)</b> |                 |                           |                 |
| <b>No. : RPB 191</b>          | <b>Rev : 09</b> | <b>Eff. date : 170426</b> | <b>Sign : B</b> |

**1 Quality**

- 1.1 USP 37, 2014
- 1.2 Internal specification

**2 Additional Requirements**

- 2.1 Particle Size :  $\leq 10 \mu\text{m}$  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 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**

- 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   | <i>[Signature]</i> | 170426 |
| Checked by        | Analytical Method Assistant Manager                       | LB   | <i>[Signature]</i> | 170426 |
| Approved by       | Quality Control Manager                                   | AM   | <i>[Signature]</i> | 170426 |
|                   | Research & Development Manager                            | LB   | <i>[Signature]</i> | 170426 |
|                   | Quality Assurance Manager                                 | PM   | <i>[Signature]</i> | 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      |      |           |                |