QUALITY ASSURANCE DEPARTMENT



STANDARD OPERATING PROCEDURE

| Department: Quality Assurance | SOP No.: |
|---|-----------------|
| Title: Handling of Cable Tie with Numbering System for Issuance of Raw Materials (API) | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a Procedure for Handling of Cable Tie by IPQA during Issuance of Raw Materials from Warehouse.

2.0 SCOPE:

This SOP is applicable for Handling of Cable Tie by IPQA during Issuance of Raw Materials from Warehouse at

3.0 RESPONSIBILITY:

Officer/Executive- QA are responsible to follow the Procedure defined in this SOP.

4.0 ACCOUNTABILITY:

Head Quality Assurance shall ensure training and compliance with this SOP.

5.0 **DEFINITION:**

Not Applicable

6.0 PROCEDURE:

6.1 Receiving and Issuance of Cable tie.

- 6.1.1 On procurement of Cable tie with numbering system it shall be received by Quality Assurance Department and its record shall be maintained as per Annexure-I, titled "Receipt and Issuance Record of Cable Tie".
- **6.1.2** Cable tie with numbering system shall be used for dispensing of API (Active Pharmaceutical Ingredient) only and the color of this cable tie shall be Green.
- **6.1.3** Quality Assurance Officer/Executive shall issue cable tie to IPQA person and maintain its record as per **Annexure-I**, titled "Receipt and Issuance Record of Cable Tie".

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6.1.4 Before start of Dispensing IPQA person shall ensure availability of cable tie with numbering system in Dispensing Room.

6.2 Numbering System of Cable tie

Numbering system of cable tie used for dispensing of raw material (API) shall be

DP000001

Where,

DP : Denotes Decoding Pharma

0000001 : Denotes Serial Number of Cable tie

6.3 Usage of Cable tie

- **6.3.1** IPQA person shall verify the dispensed material for Name of Material, AR. No., Weight and Product Name, Manufacturing date, Expiry date shall be verified from respective BMR.
- **6.3.2** After verification of Raw Materials IPQA person shall use green cable tie and tied it on the poly bag containing API only.
- **6.3.3** IPQA person shall note down the number of cable tie used and maintain its usage record as per **Annexure-II**, titled "Usage Record of Cable Tie".
- **6.3.4** Before batch manufacturing concern IPQA person shall verify the Raw Material (API) against the cable tie numbering from its usage record.
- **6.3.5** In case numbering of cable tie on Raw Material (API) found mismatch with Usage Record (Annexure-II) then it shall be returned to Warehouse and dispensing to be done again for required API.

7.0 ABBREVIATIONS:

| No. | : | Number |
|------|---|------------------------------|
| SOP | : | Standard Operating Procedure |
| BMR | : | Batch Manufacturing Record |
| A.R. | : | Analytical Report |
| IPQA | : | In process Quality Assurance |

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| Mfg. Date | : | Manufacturing Date |
|-----------|---|--------------------|
| Exp. Date | : | Expiry Date |

8.0 ANNEXURES:

| ANNEXURE No. | TITLE OF ANNEXURE | FORMAT No. |
|--------------|--|------------|
| Annexure-I | Receipt and Issuance Record of Cable Tie | |
| Annexure-II | Usage Record of Cable Tie | |

9.0 DISTRIBUTION:

| Master Copy | Quality Assurance Department |
|------------------------|------------------------------|
| Controlled Copy No. 01 | Quality Assurance Department |
| Controlled Copy No. 02 | Warehouse Department |

10.0 REFERENCES:

In –House

11.0 REVISION HISTORY:

| Revision No. | Change Control No. | Details of Changes | Reason of Changes | Effective Date | Done By |
|--------------|-----------------------|-----------------------|----------------------|----------------|---------|
| 00 | | Not Applicable | New SOP | | |



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ANNEXURE-I

RECEIPT AND ISSUANCE RECORD OF CABLE TIE

| Date of | Numbering | Numbering of Cable Tie Received By | | | Issuance of Cable Tie | | | |
|-----------|-----------|------------------------------------|--|---------------------|------------------------|--------------------------|----------------------------|--|
| Receiving | From | То | | Date of Issuance | Numbering of Cable tie | Issued By Sign & Date | Received By Sign & Date | |
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ANNEXURE-II

USAGE RECORD OF CABLE TIE

| Date | Used in Product/Raw Material | B. No./AR No. | Mfg. Date | Exp. Date | Cable Tie Number | Cable Tie Used By Department | Concern Department Sign & Date | Verified By IPQA Sign/Date |
|------|---------------------------------|---------------|-----------|-----------|------------------|---------------------------------|--------------------------------------|----------------------------------|
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