QUALITY ASSURANCE DEPARTMENT



#### STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
<b>Title:</b> 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