



STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	SOP No.:
Title: Procedure for Inactivation of Steroids	Effective Date:
Supersedes: Nil	<b>Review Date:</b>
Issue Date:	Page No.:

## **1.0 OBJECTIVE:**

To lay down a Procedure for Inactivation of Steroids.

## **2.0 SCOPE:**

This SOP is applicable for Inactivation of Steroids at .....

## **3.0 RESPONSIBILITY:**

Quality Assurance (Officer/Executive): Preparation, issuance & retrieval of this SOP.

## 4.0 ACCOUNTABILITY

Head Production: To ensure effective implementation of this SOP.

Head QA: To impart training and ensure that activity is in compliance with this SOP.

#### 5.0 **DEFINITIONS**:

NA

## 6.0 PROCEDURE

#### 6.1 Procedure for collection and inactivation of residual sample

- **6.1.1** Residual sample shall be collected from sampling area, dispensing area, manufacturing, Finished product and scrap.
- **6.1.2** Collect the residual sample in SS bucket, add 10% Sodium Hydroxide Solution leave for 1 hour.
- 6.1.3 Add sufficient Hydrochloric acid to neutralize the solution to set pH 7.0.
- **6.1.4** QC shall analyze the sample as per SOP No. ..... (Procedure for Verification of Steroids Inactivation).
- **6.1.5** All the contact parts of machinery shall be clean as per respective SOP and final rinse sample shall be provided to QC for testing.
- **6.1.6** Sample shall be analyzed for following tests:
  - **6.1.6.1** Description clear, colorless liquid.





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6.1.6.2 Detection- limit is "not detected"

# 7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QC	Quality Control
QA	Quality Assurance
Pvt.	Private
Ltd.	Limited
TOC	Total Organic Count
NMT	Not More Than

## 8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMT No.
Annexure-I	List of Steroids	

## 9.0 DISTRIBUTION:

- Master Copy
  Quality Assurance Department
- Controlled Copy No.01 Head Quality Control
- Controlled Copy No. 02 Head Production

## **10.0 REFERENCES:**

In House

# **11.0 REVISION HISTORY:**

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





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## ANNEXURE-I LIST OF STEROIDS

S.No.	Name of Raw Material