



## STANDARD OPERATING PROCEDURE

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

### 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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**ANNEXURE-I**  
**LIST OF STEROIDS**

<b>S.No.</b>	<b>Name of Raw Material</b>