



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Procedure for Inactivation of Steroids	Effective Date:
Supersedes: Nil	Review Date:
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 No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE-I
LIST OF STEROIDS

S.No.	Name of Raw Material