DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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:

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6.1.6.1 Description – clear, colorless liquid.

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