PROCEDURE FOR VERIFICATION OF STEROIDS ACTIVATION

1.0 OBJECTIVE:

To lay down a Procedure for Verification of Steroids Inactivation.

2.0 SCOPE:

This SOP is applicable for Procedure for Verification of Steroids Inactivation at ……..

3.0 RESPONSIBILITY:

Quality Control (Officer/ Executive): Preparation of this SOP.

Quality Assurance (Officer/ Executive): Issuance & Retrieval of this SOP.

4.0 ACCOUNTABILITY

Head QC: 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 After Inactivation of Steroids as per SOP, IPQA person sample shall be given in QC for analysis.

6.2 Below mention Steroids Used in Manufacturing at ……..

6.2.1 Hydrocortisone Sodium Succinate

6.2.2 Dexamethasone

6.2.3 Betamethasone

6.2.4 Nandrolone Decanote

6.3 To Verify the Inactivation of Steroids as below methods.

6.3.1 Verification for Hydrocortisone Sodium Succinate

6.3.1.1 Description: A clear colorless liquid

6.3.1.2 Detection: By UV-Spectrophotometer

6.3.1.3 First auto zero the instrument. After that take the blank water sample in both cell and scan the blank water sample in the range of 200-400 nm and again auto zero the Instrument.

6.3.1.4 After that fill the sample in one cell of instrument and scan the sample in the range of 200-400 nm.

6.3.1.5 Limit: No detection found in sample at specific absorbance at 200-400 nm and 248 nm.

6.3.2 Verification for Dexamethasone

6.3.2.1 Description: A clear colorless liquid

6.3.2.2 Detection (By UV Spectrophotometer)

6.3.2.3 First auto zero the instrument. After that take the blank water sample in both cell and scan the blank water sample in the range of 200-400 nm and again auto zero the Instrument.

6.3.2.4 After that fill the sample in one cell of instrument and scan the sample in the range of 200-400 nm.

6.3.2.5 Limit: No detection found in sample at specific absorbance at 200-400 nm and 238 nm.

6.3.3 Verification for Betamethasone

6.3.3.1 Description: A clear colorless liquid

6.3.3.2 Detection (By UV Spectrophotometer):

6.3.3.3 First auto zero the instrument. After that take the blank water sample in both cell and scan the blank water sample in the range of 200-400 nm and again auto zero the Instrument.

6.3.3.4 After that fill the sample in one cell of instrument and scan the sample in the range of 200-400 nm.

6.3.3.5 Limit : No detection found in sample at specific absorbance at 200-400 nm and 241 nm.

6.3.4 Verification for Nandrolone Decanote

6.3.4.1 Description: A clear colorless liquid

6.3.4.2 Detection (By UV Spectrophotometer):

6.3.4.3 First auto zero the instrument. After that take the blank water sample in both cell and scan the blank water sample in the range of 200-400 nm and again auto zero the Instrument.

6.3.4.4 After that fill the sample in one cell of instrument and scan the sample in the range of 200-400 nm.

6.3.4.5 Limit: No detection found in sample at specific absorbance at 200-400 nm and 240 nm.

6.3.4.6 If absorbance found in wash water during scanning immediately informed to QC Head & QA Head.

6.3.4.7 Concern person repeat the Inactivation of Steroids as per respective SOP.

6.3.4.8 After that IPQA person collect the sample again and submitted to QC dept for re-analysis.

6.3.4.9 After re-analysis of sample the result found satisfactory than Quality control Head or his designee proceed the report.

PROCEDURE FOR VERIFICATION OF STEROIDS ACTIVATION

7.0 ABBREVIATIONS:

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

8.0 ANNEXURES: NA

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		