STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Steroid Products in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure of Handling of Steroid Products in Quality Control department.

2.0 SCOPE:

This SOP is Applicable to Handling of Cross Contamination of Steroid Products in Quality Control.

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3.0 RESPONSIBILITY:

Officer / Executive – QC

4.0 ACCOUNTABILITY:

Head - QC

5.0 PROCEDURE:

5.1 DEFINITION:

"Risk Assessment' need to carry out the Assessment of Risk and to Select and Maintain measures Where exposure to any Potent Drugs i.e. Steroid may create a Health Risk to any person or can result in cross-contamination during Analysis in Quality Control and Microbiology Department.

5.2 ASSESSMENT OF RISK:

5.2.1 The main features of a Facility are described in full since there are elements pertinent to Laboratory Design and to establishing Local Rules.

5.2.2 The Laboratory should be easy to clean Bench Surfaces should be impervious to water and resistant to Acids, Alkalies, Solvents and Disinfectants.

5.2.3 Effective Disinfectants should be available for immediate use in the event of a spillage.

5.2.4 If the laboratory mechanically ventilated, it is preferable to maintain an inward flow of air while work is in progress by extracting room air to atmosphere.

5.2.5 The Laboratory Door should be closed when work is in progress.

5.2.6 Laboratory Coats or Gowns should be worn in the Laboratory and removed when leaving the Laboratory Area.

5.2.7 Personal Protective equipment including protective clothing, must be stored at well-defined Place checked and cleaned at suitable intervals and repaired/replaced if found to be defective.

5.2.8 Personal Protective equipment which may be contaminated must be removed on leaving the working area. Kept apart from uncontaminated clothing and decontaminated and cleaned or if necessary, destroyed.

5.2.9 Eating, Chewing, Drinking, Taking Medication, Smoking, Storing Food and applying Cosmetics should be forbidden.

5.2.10 Mouth Pipetting should be forbidden.

5.2.11 The Laboratory should contain a basin or sink that can be used for hand washing.

5.2.12 Hands should be decontaminated immediately when contaminated is suspected and before leaving the Laboratory.

5.2.13 Bench Tops should be cleaned after use.

5.2.14 Used Glassware and Other Materials awaiting disinfection should be stored in a safe manner. pipettes, for example, if placed in disinfectant should be totally immersed.

5.2.15 Contaminated Materials whether for recycling or disposal, should be stored and transported in robust and leak-proof containers without spillage.

5.2.16 All Waste Material, if not to be incinerated, should be disposed off safely by other appropriate means.

5.2.17 Accidents and Incidents should be immediately reported to and recorded by the person responsible for the work or other designated person.

5.2.18 There are some additional points which are statutory requirements to operate a laboratory at this level, over and above those described for laboratory Containment Level 1, which will represent the minimum standard for safe handling of Chemical and micro-organism in Quality Control and Microbiology Laboratory respectively. The additional features required for a Laboratory to operate at Containment Level 2 are as follows:

5.2.19 Access to the laboratory is restricted to authorized persons.

5.2.20 If the Laboratory is mechanically ventilated, it must be maintained at an air pressure negative to atmosphere while work is in progress.

5.2.21 Bench surface must be impervious to water, easy to clean and resistant to Acids, Alkalies, Solvent and Disinfectants.

5.2.22 There must be surface storage of biological Agents.

5.2.23 The Laboratory should be Decontaminated immediately when contamination is suspected, after handling infective agents, and before leaving the Laboratory suite.

5.2.24 An Autoclave for the sterilization of waste materials should be readily accessible without spillage.

5.2.25 There should be a means for the safe collection, storage and disposal of contaminated waste.

5.3 CONTROL MEASURES IN QUALITY CONTROL LABORATORY:

5.3.1 Handling of Steroid samples separately, by Qualified Trained Person.

5.3.2 Maintaining separate receiving trays/cabinets provide with proper identified Label.

5.3.3 Use of separate Glassware with proper cleaning procedure by using Extran MA 02 Neutral solution for Decontamination.

5.3.4 Assigning of separate and well defined place for testing.

5.3.5 Dedicated person for handling the Steroid products.

5.3.6 Use of appropriate aprons during testing need to be decontaminated before reuse and to maintain its record.

5.3.7 Equipment HPLC, used for testing to be verified for traceability before reuse for any other General Products.

5.3.8 Use of Hand, Gloves / nose Masks as a protective garment to prevent contact and inhalation.

5.3.9 Decontaminate the lab coat before reuse.

5.3.10 Hand should be decontaminated immediately when contamination is suspected after handling infective agents and before leaving the laboratory.

5.3.11 Decontamination of S.S. containers of Cleaned Aseptic Area Garments/sample shall be performed as per respective SOP before Transferring from Steroid.

5.4 CONTROL MEASURE IN MICROBIOLOGY LABORATORY:

5.4.1 Maintain separate receiving trays with proper status label for steroid products.

5.4.2 Preparation of sterility shall be separate by dipping the vials of dry powder injection of Steroid in a different container of IPA with proper status Labeling.

5.4.3 Sterility shall be performed at a time only for Steroid.

5.4.4 Switch over of steroid shall be with proper cleaning by use of disinfectant i.e. Alcohol and maintaining its record.

5.4.5 Assignment of separate Laminar Work Station with separate room for Steroid.

5.4.6 After sterility of used Glassware to be Decontamination with Extran MA 02 Neutral.

5.4.7 Dedicated Aprons with different colour codes for Steroid shall be used for handling of Steroid products.

5.4.8 Used Apron / Garment shall be followed by surface monitoring of garments and testing for the presence/absence of Steroid products. Last rinse water shall be tested for absence of steroids and to maintain records.

5.4.9 Remaining samples shall be sent to ETP for disposal in a polybag (Black Coloured) with proper status Labeling.

5.5 EVALUATION OF RISK ASSESSMENT:

5.5.1 We can evaluate by following the right procedure such that accident of cross contamination is avoided.

5.5.2 It can also be evaluated by effective monitoring whereby result are minimizing the risk .

5.5.3 It also depends upon the timely assessment of records and procedure.

6.0 REFERENCES:

Not Applicable

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Quality Control Assurance
- Master Copy Quality Assurance

9.0 ABBREVIATIONS:

ETP	Effluent Treatment Plan
HPLC	High Performance Liquid Chromatography
IPA	Isopropyl Alcohol
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
S.S	Sieve Size
SOP	Standard Operating Procedure

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By