SOP FOR RISK ASSESSMENT IN HANDLING OF CEPHALOSPORING & PENICILLIN PRODUCTS IN QUALITY CONTROL DEPARTMENT

1.0 OBJECTIVE:

To lay down a Procedure of Risk Assessment in Handling of Cephalosporin and Penicillin Products in Quality Control Department.

2.0 SCOPE:

This SOP is Applicable to Elaborate the Risk Assessment for Handling of Cross Contamination of Cephalosporin and Penicillin Products in Quality Control Area.

3.0 RESPONSIBILITY:

Officer / Executive-QC / Microbiologist

4.0 ACCOUNTABILITY:

Head-QC

5.0 PROCEDURE:

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. Penicillin, Cephalosporin may create a Health Risk to any person or can result in Cross-Contamination during Analysis in Quality Control and Microbiology Department.

5.1 ASSESSMENT OF RISK:

5.1.1 **CONTAINMENT LEVEL 1:** The main features of a Containment Level 1 Facility are described in full since there are elements pertinent to Laboratory Design and to establishing Local Rules.

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

5.1.1.2 Effective Disinfectants should be available for immediate use in the event of a Spillage.

5.1.1.3 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.

5.1.1.4 All procedures should be performed so as to minimize the production of Aerosols.

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

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

5.1.1.7 Personnel Protective Equipment, including protective clothing, must be stored well-defined place, checked and cleaned at suitable intervals and repaired/replaced if found to be detective.

5.1.1.8 Personnel 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.

5.1.1.9 Eating, Chewing, Drinking, Taking Medication, Smoking, Storing Food and applying cosmetics should be forbidden.

5.1.1.10 Mouth Pipetting should be forbidden.

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

5.1.1.12 Hands should be decontaminated immediately when contamination is suspected and before leaving the laboratory.

5.1.1.13 Bench Tops should be cleaned after use.

5.1.1.14 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.

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

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

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

5.1.2 **CONTAINMENT LEVEL 2:** There are some additional points which are statuary 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 Chemicals and micro-organisms in Quality Control and Microbiology Laboratory respectively. The additional features required for a laboratory to operate at Containment Level 2 are as follows:

5.1.2.1 Access to the Laboratory is restricted to Authorized Persons.

5.1.2.2 There must be specified Disinfection Procedures.

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

5.1.2.4 Bench surfaces must be impervious to water, easy to clean and resistant to Acids, Alkalies, Solvents and Disinfectants.

5.1.2.5 There must be safe storage of Biological Agents.

5.1.2.6 Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet or isolator, or be otherwise suitably contained.

5.1.2.7 The laboratory should contain a washbasin near the exit that can be easily be operated without any hindrance.

5.1.2.8 Hands should be **Decontaminated** immediately when contamination is suspected, after handling infective agents, and before leaving the laboratory.

5.1.2.9 An autoclave for the sterilization of waste materials should be readily accessible in the same building as the laboratory, preferably in the laboratory suite.

5.1.2.10 Materials for autoclaving should be transported to the autoclave in robust containers without spillage.

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

5.2 CONTROL MEASURES IN QUALITY CONTROL LABORATORY:

5.2.1 Handling of Penicillin and Cephalosporin samples separately, by Qualified Trained Person.

5.2.2 Maintaining separate receiving trays / Cabinets provided with proper Identified Label.

5.2.3 Use of separate Glassware with proper cleaning procedure by using 0.1 % NaOH solution for Decontamination.

5.2.4 Assigning of separate and well defined place for testing.

5.2.5 Dedicated person for handling the Penicillin and Cephalosporin Products, not the General Products.

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

5.2.7 Equipment HPLC, used for testing to be verified for traceability before reuse for any other General Products (Non Penicillin and Penicillin Product)

5.2.8 Use of Hand Gloves/Nose Masks as a protective garment to prevent contact and inhalation.

5.2.9 **Clean Up Method:** Remaining/Left Out Samples shall be properly labeled and disposed off.

5.2.10 Glassware cleaning shall be with particular detergent.

5.2.11 Dedicated Aprons with different Colour Codes (White Apron with Red Colour Strips for Penicillin Products and White Apron with Orange Colour Strips for Cephalosporin Products) shall be used for handling of Penicillin and Cephalosporin Products.

5.2.12 Decontamination of Lab Coat before reuse.

5.2.13 Hands should be **Decontaminated** immediately when contamination is suspected, after handling infective agents, and before leaving the laboratory.

5.2.14 Decontamination of S.S. containers of Cleaned Aseptic Area Garments/ Samples shall be performed as per respective SOP before transferring from Cephalosporin/ Penicillin block.

5.3 CONTROL MEASURES IN MICROBIOLOGY LABORATORY:

5.3.1 Maintain separate receiving trays with proper Status Label for Penicillin, Cephalosporin and General Products.

5.3.2 Preparation of Sterility shall be separate, by dipping the Vials of Dry Powder Injection of Penicillin and Cephalosporin in a different container of IPA with proper Status Labelling.

5.3.3 Sterility shall be performed at a time only for Penicillin or Cephalosporin.

5.3.4 Switch over of Penicillin to Cephalosporin shall be with proper cleaning by use of disinfectant i.e. Alcohol and maintaining its record.

5.3.5 Assignment of separate Laminar Work Station with separate room for penicillin and cephalosporin products.

5.3.6 After sterility, used Glasswares to be decontaminated with 0.1 % NaOH.

5.3.7 Dedicated Aprons with different Colour Codes (White Apron with Red Colour Strips for Penicillin Products and White Apron with Orange Colour Strips for Cephalosporin Products) shall be used for handling of Penicillin and Cephalosporin Products.

5.3.8 Used Apron / Garments to be decontaminate before use.

5.3.9 Decontamination of garment shall be followed by surface monitoring of garments and testing for the presence / absence of Penicillin and Cephalosporin products. Last Rinse Water shall be tested for absence of Penicillin and to maintain records.

5.3.10 Remaining samples shall be disposed off by packing in a poly bag (Black Coloured) with proper Status Labelling.

5.3.11 **Decontaminate** the contaminated media in the Autoclave meant for Discarding Media and dispose of in a safe manner by using a proper polybag and tying a knot of polybag mouth affix the Status Label.

5.4 EVALUATION OF RISK ASSESSMENT:

5.4.1 We can evaluate by following the right procedure, such that the accidents of cross contamination is avoided.

5.4.2 It can also be evaluated by effective monitoring whereby results are minimizing the risk.

5.4.3 It also depends upon the timely assessment of records and procedures.

6.0 REFERENCES:

Not Applicable

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

• Controlled Copy No. 01	Head Corporate Quality Assurance
• Controlled Copy No. 02	Head Quality Assurance
• Controlled Copy No. 03	Head Quality Assurance
• Master Copy	Corporate Quality Assurance Department

9.0 ABBREVIATIONS:

No.	Number
QA	Quality Assurance
QC	Quality Control
HPLC	High Performance Liquid Chromatography
IPA	Isopropyl Alcohol

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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