STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Impact Assessment for Equipment /System	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for the Impact Assessment of Critical Equipment / System.

2.0 SCOPE:

This procedure shall be applicable to all the critical Equipment / System of different department as Production, Warehouse, Quality Control, Quality Assurance and Engineering.

3.0 RESPONSIBILITY:

3.1 Associate Officer and above of QA dept. shall be responsible for the preparation of this SOP.

3.2 Associate Officer and above of Validation team shall be responsible for analyzing the Impact of the equipment/system.

3.3 Head QA shall be responsible for implementation of this SOP.

4.0 ACCOUNTABILITY:

Head QA

5.0 PROCEDURE:

5.1 On finalization of equipment / system list, Impact assessment shall be done for all the equipment / system to evaluate their impact on product quality based on its relation to the following four conditions:

5.1.1 Product exposure.

5.1.1.1 Equipment in direct contact of product i.e. direct contact surfaces.

5.1.1.2 Equipment / system generating utility for product processing e.g. Water, clean steam or HVAC system.

5.1.1.3 Equipment involved in preventing product exposure e.g. Isolator, Sealing machine.

5.1.2 Involvement in product processing.

5.1.3 Automatic control on process parameter.

5.1.4 Generation and/or processing of GxP critical data.

5.2 Impact Assessment is used as a tool to identify systems / equipment to be qualified.

5.3 For carrying the impact assessment the following sequence is followed

5.3.1 List of equipment / system shall be checked for its completeness.

5.3.2 Each equipment / system shall be identified for type of impact it has on the product quality i.e. direct, indirect or no impact.

5.3.2.1 **Direct Impact:** A "Direct Impact System" is an equipment, system or device, which is directly involved in the manufacturing, packaging and holding of the drug substance or product and shall have a direct impact on product quality. Equipment / system that come under any of the four categories mentioned in section 5.1 shall be considered as Direct Impact equipment / system.

5.3.2.2 **Indirect Impact:** An "Indirect Impact System" is equipment, system or device, which is not directly responsible for improving, altering or maintaining product quality, and shall be used as a measure of extra precaution and failure of which may contribute to the failure of product quality.

5.3.2.3 **No Impact:** A "No Impact System" shall not have any impact, neither directly nor indirectly, on product quality.

5.3.3 Equipment with complex systems, identified as having direct impact or indirect impact on the product quality shall be subjected to the complete validation cycle i.e. qualification steps starting from Design Qualification (DQ) followed by Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ). Whereas for equipment having direct impact on product quality but are simple, complete qualification cycle may not be required and it may be reasonable to combine IQ and OQ to a brief qualification step named as Installation-Operational Qualification (IOQ).

5.3.4 Equipment identified, as having indirect impact on the product quality shall be subjected to a brief qualification activity comprising of installation checks for major components, instruments & utilities and required operational checks. This qualification activity shall be

named as Installation and Operation Qualification (IOQ). Whereas depending upon the complexity of the Equipment / System, qualification requirement can be accessed and enhanced qualification activities may be done.

5.3.5 Equipment identified, as having no impact on the product quality shall not be subjected to any qualification activity.

5.4 Format for Impact assessment / Validation matrix is illustrated in the following Table

TABLE 1

Serial No.	Description	Quantity	Equipment ID Number	Room No.	No Impact	Indirect Impact	Direct Impact	SOP (O)	SOP (M)	SOP (CAL)	SOP (C)	SOP (T)	URS Protocol No.	FRS Protocol	DQ Protocol No.	IQ	IQ Protocol No.	OQ	OQ Protocol No.	IOQ	IOQ Protocol No.	PQ	PQ Protocol No.	Final Report

6.0 REFERENCES:

Not Applicable.

7.0 ANNEXURES:

Not Applicable.

8.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
Dept.	:	Department
QA	:	Quality Assurance
QC	:	Quality Control
HVAC	:	Heating Ventilation and Air Conditioning