STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Impact Assessment of Process Variables on Product Quality	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE

To assess the impact of process variables on quality of product prior to carrying out process validation.

2.0 SCOPE

2.1 Applicable to different stages of manufacturing for product to be validated at ……..

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 ICH Q8: Pharmaceutical Development

3.2 Attachments

3.2.1 Attachment-I: Process Variable Impact Analysis

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Critical Process Parameters:** A process parameter whose variability has an impact on a critical quality attribute and therefore shall be monitored or controlled to ensure the process produces the desired quality.

4.2 Abbreviations

4.2.1 PC: Product Code

4.2.2 QbD: Quality by Design

4.2.3 R&D:Research and Development

4.2.4 VMP:Validation master plan

5.0 RESPONSIBILITY:

5.1 Quality Assurance:

5.1.1 Assessment of impact of the process variables on quality parameters.

5.1.2 Preparation and approval of process variable impact analysis.

5.1.3 Preparation of the product assessment/validation/verification protocol for execution of the validation.

5.1.4 Maintenance of the process variable impact analysis documentation.

5.2 Production:

5.2.1 Assessment of impact of the process variables on quality parameters.

5.2.2 Preparation of process variable impact analysis.

5.3 Quality Assurance Head:

5.3.1 To ensure implementation of the defined procedure.

5.4 Plant Head:

5.4.1 To ensure implementation of the defined procedure.

6.0 Distribution:

I. Quality Assurance

II. Production

7.0 PROCEDURE:

7.1 Identification of Critical process parameters is needed to carry out process validation.

7.2 This SOP will not be applicable in case of product development following the QbD approach. In such cases, R&D shall provide the critical process parameters and Critical Quality attributes.

7.3 In case the critical process parameters need to be identified, an impact analysis shall be carried out for all process variables against the quality parameters.

7.4 Numbering of process variable impact analysis document shall be done in following manner,

PVIA/PC

Where,

PVIA: Process Variable Impact Assessment

PC: Product code

7.5 Stage wise manufacturing process flow shall be addressed in process variable document and stepwise impact analysis shall be carried out and same shall be recorded in Attachment-I.

7.6 In case of same dosage form / process of product, common variable impact analysis shall be prepared and same shall be recorded in the report by addressing the impact on quality of product with the changes as addressed in Validation Master Plan (VMP) for assessment / validation / verification criteria.

7.7 For each process variable, effect on quality of parameter to be assessed and rated as no impact, minor impact and major impact by relative numbers as 0, 1 and 2 respectively.

7.7.1 No impact (0) refers to the parameters which do not impact the quality of the product. For such parameters additional challenges are not required in assessment / validation study.

7.7.2 Minor impact (1) refers to the parameters which may impact the quality of product directly or indirectly but shall be monitored throughout batch manufacturing.

7.7.3 Major impact (1) refers to the parameters which have potential to affect the quality of the product directly. For such process variables critical control shall be established during validation and recording of same shall be done in product assessment / validation protocol.

7.7.4 This document shall be prepared only once. However if there is any change in process / process variable of product, same shall be assessed using the impact assessment stage of the change control and shall be reviewed and revised as the process variables are common for dosage form.

7.7.5 The completed impact assessment form shall be approved by Head Quality Assurance.

7.7.6 The approved copy of this document shall be maintained along with master product assessment / validation protocol.

7.7.7 Based on above analysis, manufacturing stage and process variables in the manufacturing process are selected for validation. The reference of this assessment shall be included in the respective product assessment / validation protocol.

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

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Attachment-I

	PROCESS VARIABLE IMPACT ANALYSIS	
Document No.:	**PRODUCT NAME:**	**Block:**
Version No.:		**Supersedes:**
Product Code:		**Page ___ of ___**

1.0 Objective:

To evaluate the manufacturing process for selection of process variables for the assessment/validation exercise by assessing the impact of process variables on the quality attributes of the product. This document will act as a base for selecting the stages of manufacturing for the assessment/validation in the assessment / validation protocol.

2.0 Scope:

This document is applicable to the (product name) product manufactured at ……

3.0 Methodology:

1. Review the process flow for the manufacturing process covering the steps involved in the manufacturing of the drug product.
2. Identify the process variables for the individual manufacturing stage.
3. Identify the changes addressed in VMP for assessment/validation/verification and accordingly the impacted variables having impact on quality of product.
4. Identify the quality attributes or parameters used for monitoring and evaluating the product quality.
5. Assess the process variables from individual stages of the manufacturing against the quality parameters so as to get the critical process parameters which have direct impact on the quality of the product. Such parameters are to be validated during the assessment/validation study.
6. Assess the impact of process variables on quality parameters on scale of 0, 1 and 2.

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Where,

0 – No impact

1 – Minor

2 – Major

7. On assessment the conclusion shall be drawn evaluating the manufacturing stages to be validated.

8. The form shall be then made as an attachment to the master product assessment/validation protocol.

Stages/ Process	Process Variables	Quality Parameters which can be affected					Justification of Assessment	Decision on Validation/ In-process Monitoring

0: No Impact **1: Minor** **2: Major**

4.0 Conclusion:

Based on the data obtained during the process variables impact analysis on product quality, it is observed that process of _____, _____ and _____ are the major stages for manufacturing of _____ product and it is concluded that the process _____, _____ and _____ to be validated at specified processing condition and equipment.

5.0 Recommendation:

It is recommended to validate the process of _____for _____ product. The _____ parameters are critical process parameters, _____ are Critical Quality Attributes and same shall be evaluated during Validation / Assessment.

Done By (Sign / Date)	Done By (Sign / Date)	Checked By (Sign / Date)	Approved By (Sign / Date)
Production	**Quality Assurance-Validation**	**Production Head**	**Quality Assurance Head**