	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Preparation, validation, usage and control of Calculation sheets.

2.0 SCOPE:

This SOP is applicable for Preparation, validation, usage and control of calculation Sheets for calculation of analytical results in Quality control department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control

Head – Quality Control

4.0 PROCEDURE:

4.1 Preparation of calculation sheets:

4.1.1 Calculation sheets shall be prepared for Assay, Dissolution and Dissolution profile, Related substances, Uniformity of dosage units etc.

4.1.2 Prepare the calculation sheet by using Microsoft Excel.

4.1.3 Format the cells by creating variables as required for the calculation of Individual tests.

4.1.4 Protect those cells where no variables/readings needs to be entered or where formula has been created for calculation of results.

4.1.5 Use the format as given in the current version of Annexure – I (Example for Assay test).

This format of calculation sheet indicates the detailed calculation for assay as per the following formula:

$$\text{Assay} = \frac{\text{Sample area}}{\text{Standard area}} \text{ X } \frac{\text{Std dilution}}{\text{Spl dilution}} \text{ X } \frac{\text{Potency}}{100} \text{ X Factor X } \frac{\text{Avg. wt.}}{\text{Label claim}}$$

(mg / unit dosage form)

4.1.6 Depict the above formula in one cell by selecting cells, which contains formula raw data.

4.1.7 In similar, Bracketing standard calculation shall be performed as described in the above procedure.

4.1.8 Maintain a list of calculation sheets for analysis in the format as given in Annexure – II.

4.1.9 Calculation sheet number shall be assign as per following procedure:

	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

XX/YY-ZZZ

XX　　= QC(Quality Control)

YY　　= CS (Calculation sheet)

ZZZ　　= 001 (Serial number)

For example:

QC/CS-001

Where,

QC - Department (Quality control)

CS - Excel sheet name (Calculation sheet)

001 - First number of Calculation sheet.

4.1.10　Any necessary change in the calculation/calculation sheet shall be done by QC Head or his designee only.

4.2　Validation:

4.2.1　Perform validation for every newly prepared calculation sheet prior to use, by using 3 batches data with the result obtained by validated calculator.

4.2.2　Incase of excel sheet of analytical method verification, verify the result of single batch/study with the result obtained by validated calculator.

4.2.3　Verify the each excel sheet every two year and document.

4.2.4　If any changes in calculation formula of excel sheet then re-validate the same excel sheet before implementation.

4.2.5　Perform calculation using both calculation sheet and a validated calculator.

4.2.6　Record the calculations and observations in the format as given in Annexure – III.

4.2.7　**Acceptance Criteria:**

4.2.7.1　The results obtained using the calculator should not differ from the results reported using the calculation sheet. (Rounded off to the same digits).

4.2.8　Check for the protection of inactive cells in the calculation sheet. The protected cells should not allow feeding of any data.

4.2.9　After completion of validation, approval will be done by QC Heads after Verification of the calculation sheet and the data.

	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

STANDARD OPERATING PROCEDURE		
Department: Quality Control		**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department		**Effective Date:**
Supersedes: Nil		**Review Date:**
Issue Date:		**Page No.:**

4.3   Usage of Calculation Sheet:

4.3.1   Ensure that calculation sheets are used for calculation of analytical results, those for the tests mentioned, as per given in Annexure – IV.

4.3.2   Individual User ID and Passwords for all calculation sheets shall be generated for all the analysts.

4.3.3   Open the folder "QC Calculation Sheets" available in the computers dedicated   for the usage.

4.3.4   Select and open the sub-folder identified by the test name for which Calculation needs to be performed from the above main folder.

4.3.5   Open the calculation sheet identified by the test name by selecting the User ID and entering the password.

4.3.6   Enter Product name, Batch number, A.R.No, STP Number, stage in the respective columns provided in calculation sheet or as applicable.

4.3.7   Enter the variables like Area, Absorbance, Weight, Dilution and Potency of Working Standard / Reference Standard etc., Factors or as applicable in space provided for the respective columns.

4.3.8   Check the results for compliance against specification limits.

4.3.9   Print the calculation sheet and the same shall be attached to the respective data sheet, then submit to the reviewer for checking the Report.

4.4   Control of Calculation of Sheet:

4.4.1   The access to the Master Calculation Sheets is controlled by the Head of the

Department through a password.

4.4.2   Password shall consist of not less than six, alphanumeric number and shall be generated by Head QC or his designee.

4.4.3   The Master Calculation Sheets should be made replace once an updated version of the same is put into use.

4.4.4   Review the calculation sheets whenever the Microsoft excels base Programmer undergoes an up gradation.

4.4.5   Dedicated Computers shall be used for the calculation sheets, the file path and the user ID shall be printed at the bottom page of calculation sheet.

	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.0 ANNEXURE (S):

Annexure – I : Calculation sheet for Assay

Annexure – II : List of Master Calculation sheets validation.

Annexure – III : Record of validation data.

Annexure – IV : List of calculation sheets

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

A.R. No.: Analytical Report Number

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1.	00	---	---	New SOP	---

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I
CALCULATION SHEET FOR ASSAY (FP / STABILITY)

Quality Control Department	PRODUCT NAME	BATCH NO.	A.R.NO	STP NO.	SECTION/CONDITION	LABEL CLAIM

Working Standard No.		Valid Up to		Potency %		Avg. Weight

Standard Preparation	Weight of STD / Sample(mg)	Dilution 1	Dilution 2	Dilution 3	Dilution 4	Dilution 5	FACTOR
Sample Preparation							

Standard Area	AREA1	AREA2	AREA3	AREA4	AREA5	AREA6	AVG.AREA	STD.DEV	% RSD

RESULT		
Sample Area	Assay/mg/Tab	Assay (%)
INJ 1		
INJ 2		
Mean		

BRACKETING CALCULATION	
BKT.AREA	
AVERAGE	
STD.DEV	
% RSD	

Prepared By: Checked By:
Date: Date:

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE II
LIST OF CALCULATION SHEETS-QUALITY CONTROL ANALYSIS

S.No.	Test Name	Calculation sheet Number	Validated on	Next due date of Validation	Remarks

Prepared by: Checked by:

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE III
RECORD OF VALIDATION OF DATA

Test	:	
Test Type (specific / common)	:	
Product Name/Solution Name	:	
STP Number/ GTP Number	:	

1. Formula* (for Assay/Dissolution/DP/RS/UOD/Standardization)

* To be written for individual test.

Acceptance criteria: Results obtained using the calculator should not differ from the results reported using the calculation sheet.

Reference		Results obtained by Calculation sheet	Results observed in calculator	Difference	Passes / Fails
AR Number	Results				

2. Bracketing Standard Calculation formula = Std. deviation (Mean of replica of std. areas + B. std. area) * 100

$$\frac{\text{Std. deviation (Mean of replica of std. areas + B. std. area) * 100}}{\text{Avg. Std. area of (Mean of replica of std. areas + B. std. area)}}$$

Acceptance criteria: Results obtained using the calculator should not differ from the results reported using the calculation sheet.

Reference		Results obtained by Calculation sheet	Results observed in calculator	Difference	Passes / Fails
AR Number	Results				

3. Inactive cells protection system for data feeding: Allowed / Not Allowed
Remarks: Password Protection (Head QC Comments)

Validated by:	Verified by:	Verified by:	Approved by:
(QC)	(QC)	(QC)	(QC)

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Usage of Calculation Sheets (Validated) in Quality Control Department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE IV
LIST OF CALCULATION SHEETS

S.No.	Name of Calculation sheet	Format No.
1.	Calculation sheet for Assay (By HPLC)	
2.	Calculation sheet for Raw Material Assay	
3.	Calculation sheet for Dissolution (By HPLC)	
4.	Calculation sheet for Dissolution Profile	
5.	Calculation sheet for Uniformity of Dosage Unit (By Weight Variation)	
6.	Calculation sheet for Uniformity of Dosage Unit (By HPLC)	
7.	Calculation sheet for Related substances	
8.	Calculation sheet for Dissolution (By UV)	
9.	Calculation sheet for Assay (By UV)	
10.	Calculation sheet for Uniformity of Dosage Unit (By UV)	
11.	Calculation sheet for Weight Variation	