STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: SOP for Determination of Significant Figures and Rounding Rules	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

1.1 To lay down the procedure for determination of significant figures and uniform rounding rules for the different mathematical calculations performed by operational departments.

2.0 SCOPE:

2.1 This procedure is applicable for determination of significant figures and uniform rounding rules for the different mathematical calculations performed by operational departments like Quality Control, Production, Engineering, Warehouse, Quality Assurance etc.

3.0 RESPONSIBILITY:

3.1 Personnel of concerned department to implement.

3.2 Heads of concerned departments to ensure compliance.

4.0 ACCOUNTABILITY:

4.1 Head-QA/ his designee.

5.0 PROCEDURE:

5.1 This procedure is applicable to all mathematical calculations involved in Manufacturing, Packaging, testing, calibration etc. Where tolerance limits are specified.

5.1 Significant figure determination:

5.1.1 The significant figure for a numerical value is normally given by the tolerance limit, established for the particular method, operation or process under consideration.

5.1.1.1 If the tolerance limit is expressed in decimal places, the result obtained must also be expressed or documented in decimal places following the same number of decimal places. If no decimal place is allowed, no decimal place is reported.

5.1.1.2 If it is a set value having no tolerances, (as in the case of a weighing process for a raw material) the process must be documented according to decimal places determined by the set value. The balance or any equipment used for the process must provide accuracy up to the last digit established by the current specifications.

5.1.1.3 In the case of testing methods, the significant figures are normally indicated by the methods itself. For Analytical methods follow the significant figures established by the current specifications.

5.2 **Rounding:**

5.2.1 The following rules are followed whenever rounding is needed to reduce a numerical expression or value to the last significant digit.

5.2.2 Determine the number of significant digits to be used in reported result.

5.2.2.1 Truncate to one digit beyond the significant digit required.

5.2.2.2 If that digit is 0, 1, 2, 3, or 4 - then the previous digit remains as is.

5.2.2.3 If that digit is 5, 6, 7, 8, or 9 - then the previous digit is increased by one.

5.2.2.4 In case any doubt on how to round a significant figure consult your immediate senior.

Example Table:

Specification: NMT 1.00		**Specification: NMT 25.0**		**Specification: 350.0-425.0**	
Calculated results	**Rounded off to**	**Calculated results**	**Rounded off to**	**Calculated results**	**Rounded off to**
0.950 0.951 0.952 0.953 0.954	0.95	36.90 36.91 36.92 36.93 36.94	36.9	367.10 367.11 367.12 367.13 367.14	367.1
0.955 0.956 0.957 0.958 0.959	0.96	36.95 36.96 36.97 36.98 36.99	37.0	367.15 367.16 367.17 367.18 367.19	367.2

5.2.2.5 **Exceptions:**

5.2.2.5.1 In case of reporting the result of Related Substance test result shall be reported to one decimal more than the specification limit, without rounding the figure.

5.2.2.5.2 If the last digit of reported value is smaller or equal to 4 then the results shall be considered as a “Pass”.

5.2.2.5.3 If the last digit of reported value is greater or equal to 5 then the results shall be considered as a "Fail".

5.2.2.5.4 In case of impurity limit given as single digit then results shall be reported to two decimal more than the specification limit, without rounding the figure.

5.2.2.6 **Examples:**

Parameter	Specification (%)	Calculated value (%)	Shall be reported as (%)	Pass/Fail
Related substance (Impurity)	0.1	0.1449	0.14	Pass
		0.1500	0.15	Fail
	1.0	1.0459	1.04	Pass
		1.0500	1.05	Fail
	0.10	0.1040	0.104	Pass
		0.1055	0.105	Fail
	0.100	0.1004	0.1004	Pass
		0.1005	0.1005	Fail
	1	1.0449	1.04	Pass
	4	4.0500	4.05	Fail

5.2.2.6.1 In case of impurities reporting where the results becoming 'Zero', the result shall be reported to three/four decimals without rounding off.

5.2.2.6.2 In case of reporting water content, Residue on ignition, Loss on drying, Loss on ignition & Sulphated ash where the results becoming 'Zero' after rounding off, the result shall be reported to one decimal more than the specification limit.

Examples:

Parameter	Specification (%)	Calculated value (%)	Shall be reported as (%)
Related substance (Impurity)	0.1	0.0445	0.04
		0.0051	0.005
		0.0004	0.0004
Water content, Residue on ignition, Loss on Drying, Loss on ignition and sulphated ash	1.0	0.0047	0.005
	1.0	0.0446	0.04
	0.50	0.0026	0.003
	0.50	0.0057	0.006

5.2.2.6.3 For calculating the Assay on anhydrous basis, Moisture content/LOD shall be taken in 3 decimals without rounding the calculated value, irrespective of the number of significant figures present in the specification.

5.2.2.7 Examples:

Parameter	Specification (%)	Calculated value (%)	Shall be reported as (%)	Value for assay calculation (%)
a) LOD	1.0	0.3456	0.3	0.345
b) Water content	2.0	1.7327	1.7	1.732

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5.2.2.7.1.1 In case of reporting of impurities, residue and residual solvents where the calculated result is below Limit of Quantification but above limit of detection, then the actual detected value shall be reported using rounding rules and the LOQ and LOD values shall be written in the bracket.

5.2.2.7.2 In case of reporting of impurities, residue and residual solvents where calculated result is below the limit of detection then report as below limit of detection (BLD) with the LOD values written in the bracket.

5.2.2.7.3 Where applicable (wherever disregard limit mentioned in STP), In case of reporting of related substances, the calculated result of impurity below disregard limit, the result shall be reported as ‘ Below disregard limit’(BDL) and write the disregard the limit within the bracket.

Example: If the result is 0.030% and the disregard limit is 0.05%.Report the result as ‘BDL’ (Disregard limit: 0.05%). If the disregard limit is based on peak area then it shall be converted in to percentage for reporting.

5.2.2.7.4 pH to be reported as instrument display.

Note:

(a) For LOQ and LOD values refer respective standard test procedure.

(b) For pharmacopoeia method where LOQ/LOD values are not specified, report the actual values rounded off to the decimals given in the specification. If no content is found then report as "Not Detected"

Examples:

Parameter	Specification	Calculated value	LOQ	LOD	Shall be reported as
Impurity	NMT 0.2%	0.0015%	0.03%	0.005%	BLD (LOD=0.005%)
		0.0019%	0.002%	0.001%	0.001% (LOQ=0.002%) (LOD=0.001%)
		0.0111%	0.01%	0.001%	0.01% (LOQ=0.01%) (LOD=0.001%)
		0.0123%	0.02%	Not given	0.01% (LOQ = 0.02%)
Residual solvents	NMT 100 ppm	3ppm	5ppm	0.5ppm	3 ppm (LOQ = 5 ppm) (LOD = 0.5 ppm)
		0.94 ppm	5 ppm	0.5 ppm	1ppm (LOQ=5ppm) (LOD = 0.5 ppm)
		0.495 ppm	5 ppm	0.5 ppm	BLD (LOD = 0.5 ppm)
Residue	NMT 50 ppm	2 ppm	7 ppm	0.1 ppm	2ppm(LOQ = 7 ppm) (LOD = 0.1 ppm)
		0.73 ppm	7 ppm	0.1 ppm	1ppm (LOQ = 7ppm) (LOD = 0.1 ppm)
		0.095 ppm	7 ppm	0.1 ppm	BLD (LOD = 0.1 ppm)

6.0 ABBREVIATIONS:

6.1 SOP - Standard Operating Procedure

6.2 QA - Quality Assurance

7.0 CROSS REFERENCES:

7.1 NA

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8.0 REFERENCES:

8.1 In-House

9.0 ATTACHMENTS:

9.1 NA

10.0 CIRCULATION LIST:

10.1 Quality Assurance

10.2 Production

10.3 Engineering

10.4 Quality Control

10.5 Warehouse

10.6 Personnel & Administration

10.7 Purchase

10.8 Account

11.0 REVISION HISTORY:

SOP NUMBER	REASON FOR CHANGE	VERSION NUMBER	SUPERSEDES	CHANGE CONTROL No.
	New SOP	01	NIL	NA