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1.0 PURPOSE

To define a procedure for rounding off to significant figures without affecting the safety, identity, strength, purity and quality of the products.

2.0 SCOPE

2.1 This procedure is applicable to those numbers, which can be rounded off to a significant figure without affecting the safety, identity, strength, purity and quality of the product.

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 USP, general notices: significant figures and tolerances.

3.1.2 ICH Q3B (R2) – Impurities in new drug products.

3.2 Attachments

3.2.1 Attachment –I : Rounding of results as per USP requirements.

3.2.2 Attachment–II : Reporting of Analytical results

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Significant figures**

Significant figures include all the digits in a measurement that are known with certainty as well as the last digit, which is an approximation.

The use of significant number in a result implies a given degree of confidence in that result. e.g. Rounding to 2 significant figures:

- 0.00123 become 0.0012
- 0.1 becomes 0.10 (the trailing zero indicates that we are rounding to 2 significant figures).
- 0.02084 becomes 0.021

4.1.2 **Rounding**

The process of reducing the number of significant digits in a specification.

The result of rounding is a "shorter" number having fewer non-zero digits yet similar in magnitude. Rounding off is necessary to report calculated value using same number of significant figures as in the specification limit.

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4.2 Abbreviations

4.2.1 API : Active pharmaceuticals ingredient

4.2.2 IR :Infra Red

4.2.3 QC : Quality Control

4.2.4 QA : Quality Assurance

4.2.5 STP: Standard Test Procedure

4.2.6 USP: United State Pharmacopoeia

5.0 RESPONSIBILITY

5.1 Corporate Quality Assurance

5.1.1 To ensure implementation of the procedure

5.2 QC Analyst/ QA:

5.2.1 To round off and report of analytical results

5.3 Head QA or designee

5.3.1 To ensure implementation of defined procedure.

6.0 Distribution:

I. Quality Assurance
II. Quality Control
III. Production
IV. Ware house
V. Engineering
VI. Environment, Health and safety

7.0 PROCEDURE:

7.1 General criteria

7.1.1 The specification limit is fixed and shall not be “rounded off”.

7.1.2 Analytical results observed in the laboratory shall be compared with stated limits to determine the conformance with specification.

7.1.3 The observed or calculated values will contain more figures than they are in stated limit.

7.1.4 In general, observed or calculated results are to be rounded off to the number of places after decimal that is in agreement with the limit.

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7.2 Rounding Off

7.2.1 When "rounding off" result is required, only one digit in the decimal place to the right of the last place in the limit expression shall be considered.

7.2.1.1 If the digit is smaller than 5, it is eliminated and preceding digit shall be unchanged (Limit: More than or equal to 98.0%, result 97.9456 %, rounded result is 97.9%)

7.2.1.2 If the digit is greater than 5, it is eliminated and preceding digit shall be increased by one (Rounding off to be done).

(Limit: More than or equal to 98.0%, result 97.9612 % , rounded result is 98.0%)

7.2.1.3 If the digit is 5 or equal to 5, it is eliminated and preceding digit shall be increased by one (Rounding off to be done).

(Limit: More than or equal to 98.0%, result 97.9575 % , rounded result is 98.0%)

7.2.1.4 If average of more than one result is to be taken, then for each value consider only one digit in the decimal place to the right of the last place in the limit expression. Determine the average value. Consider this whole result to the decimal place.

Based on above three cases result value.

For e.g. Result -1 : 97.9456

Result -2 : 97.9612

Result -3 : 97.9575

Average of (97.9456+97.9612 + 97.9575) /3 = 97.95476, which is to be rounded off to 98.0%.

7.2.2 Assay value shall be rounded off to only one digit after decimal i.e. 99.3% not 99.26. For detailed rounding and reporting of results refer Attachment-I.

7.2.3 Assay value of the drug product shall be in unit of measurement (e.g. mg) as well as in %.

7.2.4 Dissolution result shall be reported with whole numbers & no digit after decimal i.e. 98%, and not 98.2% of the average value of six units.

7.2.5 The related substance result shall be reported with only three digits after the decimal i.e. 0.312% and not 0.3156%.

7.2.6 Limit test results shall be reported as comply / does not comply.

7.2.7 The residual solvent data shall be reported only on whole number i.e. 315 ppm & not 314.5 ppm.

7.2.8 Uniformity of dosage limit shall be reported as minimum, maximum and Average value in case of IP, as per BP/EP/USP shall be reported as exact value with only one digit after decimal.

7.2.9 For the test where value is displayed by the instrument, report the values without rounding off. For e.g. Melting point, Refractive Index, Viscosity, Specific Optical Rotation etc.

7.2.10 LOD / Friability shall be reported with only one digit after decimal.

7.2.11 Physical parameters like hardness, thickness, average fill weight, average fill volume shall be rounded off based on the least count / accuracy of the instrument used for the analysis.

7.2.12 Rounding off shall not be done while reporting the results for endotoxin test, TOC, Conductivity & assay of vitamins.

7.2.13 Weights and area counts taken for standard and test preparation shall not be rounded off.

Note: Illustration of rounding numerical value for compression with USP requirement as per Attachment- I.

7.3 For significant figures and analytical results, refer Attachment-II to report each analytical test results.

7.4 For relative standard deviation results shall be rounded to one place.

7.5 For rounding off normality/molarity for 0.1M/N to 1M/N = four digit of decimal and 0.001M/N to 0.09M/N = five digits of decimal.

8.0 REVISION HISTORY

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

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Attachment-I
Rounding of results as per USP requirements

Compendial Requirement	Un-rounded Value	Rounded Value	Conforms
Assay limit greater than equal to 98.0 %	97.96 %	98.0 %	Yes
	97.92 %	97.9 %	No
	97.95 %	98.0 %	Yes
Assay limit less than or equal to 101.5 %	101.55 %	101.6 %	No
	101.46 %	101.5 %	Yes
	101.45 %	101.5 %	Yes
Limit Test less than or equal to 0.02 %	0.025 %	0.03 %	No
	0.015 %	0.02 %	Yes
	0.027 %	0.03 %	No
Limit Test less than or equal to 3 ppm	0.00035 %	0.0004 %	No
	0.00025 %	0.0003 %	Yes
	0.00028 %	0.0003 %	Yes

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Attachment –II
Reporting of analytical results

S.No.	Test Parameter	Presentation of Limit	Reporting of results	Example	Remarks
1.	General (applicable for all test)		Whenever rounding is done on the lower side, USP general notice, Ph. Eur., BP, IP to be referred to ensure that rounding off is not misleading to change a failing result to pass result.		This Limit in the specification shall always be taken into account while reporting any value in the COA or stability data sheets.
2.	Alcohol Content	Between 65% and 75 % Between 4.0% and 6.0%	Shall be up to the limit outlined in the specification only.	70% 5.1%	The decimal place in the specification shall be taken into account while reporting any value in the COA or stability data sheets.
3.	Assay	90.0 – 110 .0 %	Only one digit after decimal. Assay values for the drug products to be reported in mg as well as percentage.	99.2% 248.6 mg (99.4 %)	For API: Reporting shall be up to one decimal place in line with the limits (e.g. 99.1 % when the limit is 98.0 to 102.0 %)
			For low doses forms i.e. less then 1 mg – four decimal in mg	0.4854 mg	For Drug Product: The reporting shall be up to the decimal place that takes care of % value in the specification. Accordingly the reporting procedure (after decimal place) for various strengths of drug product are tabulated below: < 1mg – 4 decimals 1 mg to 9 mg – 3 decimals 10 mg to 99 mg –2 decimals 100 mg and above – 1 decimal If the result is reported in both, mg & % the unrounded recorded value will be taken into account to calculate both the above value for reporting.
4.	Assay of preservative	Preservative level: 0.01to 0.09 % 0.1 to 0.9 % 1% to 9 %	Reporting up to decimal places: Four Three Two	0.0666% 0.333% 1.11% 10.22	If in terms of % w/w or v/w, then avoid setting the specification range such as 80.0 to 120.0 % and instead propose 80 to 120 %. Accordingly, for increment of 1 % need to have a reporting up to1% of the label claim of

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S.No.	Test Parameter	Presentation of Limit	Reporting of results	Example	Remarks
		10 % or more	Two		the preservative.
5.	Average weight/ Average fill weight	200.5 mg	Shall always be reported in line with the limits.	200.5 mg	-
6.	Below limit of quantification level (BQL) Results.		Before reporting, check results against LOQ Value given in STP / Validation report. Whenever the results are below LOQ, it shall be reported as BQL and report the LOQ value as a footnote in COA / data sheet.		For reporting of the impurities below quantification limit, the current approach of reporting the impurity with a asterisk stating that it is below LOQ shall be captured along with the statement that these are to be excluded from the total related substance. The symbol of < (less than) shall not be used. Instead the same will be reported in words as 'less than' or 'Below LOQ'
7.	Below limit of Detection level (BDL) Results.		Before reporting, check results against LOD Value given in STP / Validation report. Whenever the results are below LOD, it shall be reported as BDL and report the LOD value as a footnote in COA / data sheet.		For reporting of the impurities below detection limit, the current approach of reporting the impurity with a asterisk stating that it is below LOD shall be captured along with the statement that these are to be excluded from the total related substance. The symbol of < (less than) shall not be used. Instead the same will be reported in words as 'less than' or 'Below LOD'
8.	Bulk Density	Between 2.2 – 2.4 g / ml	Shall be up to the limit outlined in the specification only (Which is generally up to one decimal place)	2.2 gm / ml	-
9.	Chloride Content	Not less than 10.9 % and not more than 11.3%	Shall be up to the limit outlined in the specification only (Which is generally up to one decimal place)	11.1 %	-
10.	Description	White to Off-White crystalline powder.	Shall be reported as per the actual observation against the specification Result shall not be reported as 'Complies' or 'not complies'	White crystalline powder.	-
11.	Disintegration Time	NMT 15 minutes	Reported in terms of minutes.	Range between 2 minutes to 3 minutes	Range shall be given as min and max time in units , minutes or seconds
12.	Drug Release (for extended release tablets)	2 hrs – 45 to 65 %	Shall be reported as whole numbers only and no digit after decimal of average.	55 % 55 %	-

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			All data presented in the stability data sheets shall have the range, in addition to mean	(48 – 62 %)	
13.	Identification (IR, UV – Vis, TLC HPLC, GC, XRD, or wet analysis)		Shall be reported as per the actual observation against the specification. The "Complies "or "not Complies shall not be used.	-	Such as IR, the IR spectra of sample shall match with standard spectrum.
14.	Impurities by thin layer chromatography	Single Impurity NMT 0.2 %	Shall be reported as per the actual observation against the specification.	Between 0.05% to 0.1 %	-
15.	Limit Test	NMT 0.002%	Shall be reported as "Complies" when same standard is used as a limit	-	Numerical values shall be provided whenever applicable, instead of writing 'Complies" The symbols like > (more than), < (less then) shall not be used. Instead the same will be reported in words as 'less than' and 'more than'.
16.	LOD / Moisture Content / Friability	NMT 2.0 % NMT 0.5 %	One digit after decimal Two digit after decimal	1.2 % 0.44 %	-
17.	Melting Point / Melting Range	56°C to 60 °C	Shall always be reported in whole numbers in line with the limits.	57°C -58°C	-
18.	Optical Rotation	Between + 15.1° to +17.5°	Shall be up to the limit outlined in the specifications only (Which is generally up to one decimal place.)	-	-
19.	Osmolarity	Between 230 & 270 Osm per liter	Shall always be reported in whole number in line with the limit.	250 Osm per litre	-
20.	Particle Size	D 90 – NMT 30 µm	Shall always be reported in whole number in line with the limit.	D 90 – 25µm	-
21.	pH	Between 5.0 to 7.0	Shall be up to the outlined in the specifications only (which is generally up to one decimal place)	5.5	-
22.	Refractive Index	Between 1.520 and 1.524	Shall be up to the limit outlined in the specifications only (which is generally up to the three decimal place)	1.522	-
23.	Related Substance / Chromatographic purity	NMT 1.5 % NMT 1.0% NMT 0.5%	Three Decimal Three Decimal Three Decimal	1.212% 0.880% 0.482%	The reporting of the impurities shall be in line with the procedure
24.	Residual solvents & organic volatile impurities	NMT 400 ppm	Shall be reported as whole numbers only and no digit after the decimal.	243 ppm	-

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S.No.	Test Parameter	Presentation of Limit	Reporting of results	Example	Remarks
25.	Residue on ignition / Sulfated ash	NMT 1.0 %	Shall be reported up to two decimal	0.05 %	-
26.	Solubility	-	Shall be reported as “complies” when same standard is used as the limit.	-	-
27.	Specific Gravity	Between 0.996 and 1.002	Reporting shall be up to the limit outlined in the specifications only (Which is generally up to three decimal place).	1.000	-
28.	Total bacterial count / Total fungal count	NMT 100 cfu / ml	Shall be reported as whole numbers only and no digit after decimal.	50 cfu / ml	Shall be reported actual value
29	Uniformity of dosage unit	85 % to 115 % as per IP requirements	Report the actual results in the COA with respect to the label claim	X% to Y% (RSD Z%)	It shall be reported as + or – X % to + or – Y % (RSD = Z%) X, Y & Z shall be reported up to one decimal place only irrespective of the strength of the dosages form.
30.	Uniformity of dosage unit (For BP/EP/USP)	Meets the requirements	Mention “Meets the requirements “in the specification. Report the actual results in the COA with respect to the label claim	L=15	It shall be reported up to one decimal place.
31.	Viscosity	Between 11and 60 centipoises	Shall always be reported in whole number in line with the limits.	25 centipoises	-