



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Procedure for the Rounding Off the Analytical test results	Effective Date:
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1.0 OBJECTIVE:

To lay down procedure for the rounding off the analytical test results to insure the uniformity in result reporting.

2.0 SCOPE:

This SOP is applicable to QC laboratory.

3.0 RESPONSIBILITY – Execution.- Executive QC
Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 GENERAL PROCEDURE:

5.1.1 Analytical results observed in the laboratory are compared with stated limits to determine whether there is conformance with compendial requirements.

5.1.2 The observed or calculated values usually will contain more significant figure than there are in the stated limit.

5.1.3 Observed or calculated result is to be rounded off to the number of places that is in agreement with the limit.

5.2 PROCEDURE FOR ROUNDING OFF FIGURES:

5.2.1 Where ever the limit is not specified and rounding off of required report the result upto two digits.

5.2.2 If the test having specific limit, report the final result on the basis of limit, the number digits after decimal points shall be same for limit and reporting value.

5.2.3 If the limit having one digit after decimal point, the result also report one digit after decimal point.

5.2.4 If the values having more figures after the decimal place the value shall rounding off as per the limit.If the limit have not decimal point the reporting value should be without decimal point.

Example : Limit : NMT 101%

Calculated Value : 100.9582%

Reporting Value : 101%

5.2.5 When rounding off is required, considered only one digit in the decimal place to the right of the last place in the limit expression.



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5.2.6 If this digit is smaller than 5, it is eliminated and the preceding digit is unchanged. If this digit is 5 or greater than 5, it is eliminated and preceding digit is increased by one.

5.2.7 If the second number after decimal place to be rounding off the value of second number depends on third number after decimal place.

5.2.8 If the third number after decimal place is 4 or below 4 the second number remains same and it shall not be changed.

5.2.9 Example : The observed value is 0.5612% and the limit is NMT 0.75%.

The value shall be rounding off the second number after decimal place, i.e. 6.

The third number after decimal place is 1, so the reporting value is 0.56%.

5.2.9 If the third number after decimal place is 5 or above 5, the second number shall be reported as one number more to the actual number.

5.2.10 Example : The observed value is 0.5672% and the limit is NMT 0.75%.

The value shall be rounding off the second number after decimal place, i.e. 6.

The third number after decimal place is 7, so the reporting value is 0.57%.

5.3 ROUNDING OFF FOR THE RESULTS OF VOLUMETRIC SOLUTIONS:

5.3.1 For 0.1 to 1M or N solutions, express the strength up to four digit after the decimal point

Example : 1M/N = 1.0000

0.2 M/N = 0.2000

5.3.2 For 0.01 to less than 0.1 M/N solutions : Express the strength up to five digits after the decimal points

Example : 0.01 M/N = 0.01000

0.05 M/N = 0.05000

5.3.3 For 0.001 to less than 0.01 M/N solutions : Express the strength up to six digits after the decimal points

Example : 0.001 M/N = 0.001000

0.005 M/N = 0.005000

5.4 ROUNDING OFF FOR THE RESULTS OF IMPURITIES

5.4.1 Rounding off the reporting results for impurities shall be three digits after the decimal point and it shall be irrespective of the limit.

Example : observed value is 0.026582%

Reporting value is 0.027%



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5.5 ROUNDING OFF FOR THE RESULTS OF ASSAY/ UNIFORMITY OF CONTENT:

5.5.1 Rounding off the reporting results for assay/ uniformity of content shall be two digits after the decimal point and it shall be irrespective of the limit.

Example : observed value is 99.06585%

Reporting value is 99.07%

5.5.2 The results obtained from these, like % RSD and individual values shall report 2 digits after the decimal point and it shall be the irrespective of the limit.

5.6 ROUNDING OFF FOR THE RESULTS OF LIMIT TEST:

5.6.1 Rounding off the reporting results for limit tests shall be follow general procedure and examples has given in the Annexure-1.

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

US Pharmacopoeia



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10.0 ABBREVIATIONS & ANNEXURES

SOP : Standard Operating Procedure

USP : United State Pharmacopeia

QC : Quality Control

No. : Number

Annexure –I: Examples For Rounding Off the reporting Results



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ANNEXURE – I

EXAMPLES FOR LIMIT TESTS

S.No.	COMPENDIAL REQUIREMENTS	UNROUNDED VALUES	ROUNDED RESULTS	CONFIRMS WITH THE REQUIREMENT
1.	LIMIT TEST \leq 0.02%	0.025%	0.03%	NO
		0.015%	0.02%	YES
		0.027%	0.03%	NO
2.	LIMIT TEST \leq 3 ppm	0.0035%	0.0004%	NO
		0.00025%	0.0003%	YES
		0.00028%	0.0003%	YES

EXAMPLES FOR IMPURITY TESTS

S.NO.	COMPENDIAL REQUIREMENTS	UNROUNDED VALUES	ROUNDED RESULTS	CONFIRMS WITH THE REQUIREMENT
1	NMT 0.5 %	0.4258	0.426%	YES
		0.00985	0.010%	YES
		0.50090	0.501%	NO

EXAMPLES FOR ASSAY/ UNIFORMITY OF CONTENTS

S.NO.	COMPENDIAL REQUIREMENTS	UNROUNDED VALUES	ROUNDED RESULTS	CONFIRMS WITH THE REQUIREMENT
<u>1</u>	NLT 99.0 % and NMT 101.0%	99.2598	99.26%	YES
		100.9948	100.99%	YES
		98.6895	98.70%	NO



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EXAMPLES FOR ASSAY IF LIMIT IS MORE THAN TWO DIGITS AFTER DECIMAL POINT (FOR LOWER CONCENTRATIONS):

S.NO.	COMPENDIAL REQUIREMENTS	UNROUNDED VALUES	ROUNDED RESULTS	CONFIRMS WITH THE REQUIREMENT
1	NLT 0.25 to NMT 0.50	0.258952	0.259	YES
		0.245851	0.246	NO
		0.500852	0.501	NO
2	NLT 0.175 to NMT 0.225	0.175981	0.1760	YES
		0.174891	0.1749	NO