

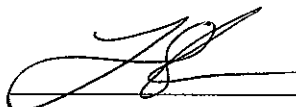
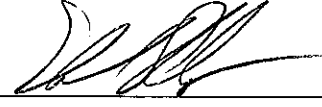
Title: Significant Figures and Rounding

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Reference: Current USP - General Notices

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	01-07-94	Original Version
2.	05-17-02	Converted to LWP format. Sec. 3.0: Changed to reflect USP criteria. Sec. 4.0: Added USP General Notice excerpt.
3.	OCT 16 2009	Revised to conform with current SOP 101. Sec. 2.6, 2.7, 2.8: added. Sec. 3.0: Renumbered.
4.		
5.		

<u>Prepared by</u>	<u>Date</u>	<u>Technical Review</u>	<u>Date</u>
	09/24/09		9/25/09

QA Approval/Date:  10/16/09

1.0 SCOPE AND APPLICATION

This SOP outlines the policy and procedure for determining how many significant figures should be reported and how rounding should be performed.

2.0 SIGNIFICANT FIGURES

- 2.1 The use of a given number of significant figures in a result implies a given degree of confidence in that result. Generally, the uncertainty in a result is plus or minus one in the last significant figure. That is, a two significant figure result of 46 implies that we are confident that the "true value" is between 45 and 47. A four significant figure result of 46.00 implies that we are confident that the "true value" is between 45.99 and 46.01. In the first case, the relative uncertainty is approximately 2.2%, in the second, approximately 0.022%.
- 2.2 Mathematically, the limiting factor in determining how many significant figures to carry is how many are present in each of the values used in the calculations. Generally, the value with the fewest is the sample amount. With very few exceptions, the samples are measured to two or three significant figures. Therefore, final sample results should not be reported with any more than this. To do so implies a level of certainty which is not justified. Semi-quantitative results are even less certain; in general, these should be reported to one significant figure only, unless quantitation is performed using, as a standard, a compound which is isomeric with the analyte.
- 2.3 Generally, the number of significant figures reported should relate to the precision expected for the measurement. The number reported should be at least as precise as the measurement, but too many figures should be avoided because it may give the client a false sense of error in the number.
- 2.4 Most analytical measurements have RSD's in the range of 3-10%, therefore 99% confidence limits are 9-30%. The precision will degrade as the result approaches the detection limit.

Assuming a detection limit of 1, these guidelines should be followed in reports:

<u>Result</u>	<u>Significant Figures</u>	<u>Examples</u>
>10	2-3	11, 12.3, 99
1-9.9	1-2	2, 3.5, 9

- 2.5 For very precise measurements (RSDs = 3 %), the first examples may slightly understate the certainty of the measurement, while the second and third examples may overstate the certainty. Overstating the precision is preferable to understating it.

2.6 Detection limits are always given to one significant figure.

2.7 The directions for titrimetric procedures conclude with a statement of the weight of the analyte that is equivalent to each mL of the standardized titrant. In such an equivalence statement, the number of significant figures in the concentration of the titrant should be understood to correspond to the number of significant figures in the weight of the analyte.

2.8 The number of significant figures in the labeled calculation value of a USP reference standard is a function of the use of the standard and the number of significant figures in the acceptance range or limit. Generally, Reference Standards used in assays are labeled with three significant figures and standards used in limit tests with two significant figures. Reference Standards having multiple applications in different methodologies may require separate assay-specific assignments.

3.0 ROUNDING

3.1 Round off observed or calculated values to the number of decimal places that is in agreement with the limit expression in the specification.

3.2 Numbers should not be rounded until the final calculations for the reportable value have been completed. Intermediate calculations (e.g., slope for linearity) may be rounded for reporting purposes, but the original (not rounded) value should be used for any additional required calculations. Acceptance criteria are fixed numbers and are not rounded.

3.3 When rounding is required, consider only one digit in the decimal place to the right of the last place in the limit expression. If this digit is smaller than 5, it is eliminated and the preceding digit is unchanged. If this digit is equal to or greater than 5, it is eliminated and the preceding digit is increased by 1. The Lotus spreadsheets use this method of rounding.

Examples: 33.5 rounds to 34
 33.49 rounds to 33

3.4 Illustration of Rounding Numerical Values for Comparison with Specifications:

Compendial Requirement	Unrounded Value	Rounded Result	Conforms
Assay limit $\geq 98.0\%$	97.96%	98.0%	Yes
	97.92%	97.9%	No
	97.95%	98.0%	Yes
Assay limit $\leq 101.5\%$	101.55%	101.6%	No
	101.46%	101.5%	Yes
	101.45%	101.5%	Yes
Limit test $\leq 0.02\%$	0.025%	0.03%	No
	0.015%	0.02%	Yes
	0.027%	0.03%	No
Limit test ≤ 3 ppm	0.00035%	0.0004%	No
	0.00025%	0.0003%	Yes
	0.00028%	0.0003%	Yes