The University of Iowa Dezii Translational Vision Research Group

TITLE: Definition of Raw Data and Acceptance of Electronic Documents

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Effective Date: 09 Aug 2015

Author: _____ Date: _____

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QA Approval: _____ Date: _____

A. OBJECTIVE

This SOP is to provide mathematical data reporting guidelines for permanent employees of the University of Iowa Dezii Translational Vision Research Group (DTVR) as well as for any Contractors/Consultants performing work and generating data for DTVR. This SOP is intended to assure compliance with current Good Manufacturing Practices (cGMPs).

B. APPLICABILITY

This SOP shall be performed by The University of Iowa Dezii Translational Vision Research Group (DTVR) staff and any contracted personnel under the direction of the DTVR Quality Assurance Officer.

C. REFERENCES

ASTM E29 – 08: Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
USP 35 General Notices: Section 7.0: Test Results
DTVR Quality Manual

D. PROCEDURE

1. Calculating and Reporting Rules

1.1. When calculating and reporting values, the final number of significant digits should be based on the acceptance criteria for that value. Acceptance criteria are considered significant to the last digit shown.

1.2. During calculations, numbers should not be rounded until the final value is obtained. Once the final value is obtained, the following rules apply:

1.2.1. If the digit to the right of the last significant digit is 4 or less, the last digit is dropped and the preceding number is left unchanged. For example, 1.441 becomes 1.44. If the digit to the right of the last significant digit is 5 greater or greater, add 1 to the last digit to be retained. For example, 1.446 becomes 1.45.

1.2.2. In adding or subtracting a number of terms, the result should have the same number of digits to the right of the decimal point as the term with the least number of such digits. For example, assuming the last figure in each term is uncertain, the sum of the following would be

00.0121
25.64
+ 01.05782
26.70992 This should be rounded to 26.71

1.2.3. In multiplication or division, the result should contain the same number of significant figures as the term with the least significant figures. For example, if multiplying the following three terms assuming the last figure to be uncertain, the answer would be:

0.0121 x 25.64 x 1.05782 = 0.328182308 and should be rounded to 0.328

Since the first term, 0.0121, has the least number of significant figures (three), the result should be reported to three significant figures.

2. Interpretation of zero

2.1. Any zero left of the digit that merely shows the location of the decimal point is not significant. For example, 0.000404 has three significant digits.

2.2. One or more final zeros to the right of the decimal point may be taken as significant. For example, 404.00 has five significant figures.

2.3. One or more final zeros as a part of a whole number (immediately to the left of the decimal point) should be considered significant unless shown by the data to be insignificant. For example, 404,000 +/- 1,000 has three significant figures; 404,000 +/- 10 has five significant figures.

2.4. Non-zero integers are always significant. For example, 23.4 g and 234 g both have three significant figures.

2.5. Captive zeros, those bound on both sides by non-zero integers, are always significant. For example, 20.05 has four significant figures and 407 has three significant figures.

2.6. Leading zeros, those not bound on the left by non-zero integers, are never significant. Such zeros just set the decimal point; they always disappear if the number is converted to powers of 10 notation. For example, 0.04 g has one significant figure; 0.00035 g has two significant figures. They can be written as 4 x 10-3 and 3.5 x 10-4 respectively.

2.7. Trailing zeros, those bound only on the left by non-zero integers, may or may not be significant. For example, 45.0 L has three significant figures; 450 L has only two significant figures.

2.8. Note: To clarify whether a trailing zero is significant, it is preferable to use scientific notation to express the final answer.

E. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document