

Accepted Manuscript

Title: Precision of the reportable value – statistical optimization of the number of replicates

Authors: Richard K. Burdick, Joachim Ermer

PII: S0731-7085(18)31574-7
DOI: <https://doi.org/10.1016/j.jpba.2018.08.062>
Reference: PBA 12193

To appear in: *Journal of Pharmaceutical and Biomedical Analysis*

Received date: 11-7-2018
Revised date: 28-8-2018
Accepted date: 31-8-2018

Please cite this article as: Burdick RK, Ermer J, Precision of the reportable value – statistical optimization of the number of replicates, *Journal of Pharmaceutical and Biomedical Analysis* (2018), <https://doi.org/10.1016/j.jpba.2018.08.062>

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



Precision of the reportable value – statistical optimization of the number of replicates

Richard K. Burdick ^{a*} and Joachim Ermer ^b

* correspondence author

a: Burdick Statistical Consulting, LLC

2311 Whistler Drive

Longmont, CO 80504 USA

RickBASU@aol.com

b: Sanofi-Aventis Deutschland GmbH

Quality Control Services Frankfurt Chemistry

Industriepark Hoechst - Bldg. D711

D-65926 Frankfurt am Main

Joachim.ermer@sanofi.com

Highlights

- Statistical models are presented that allow optimizing efficiently the replication strategy for the number of routine injections, sample preparations, and runs defined for the reportable value with respect to the confidence interval of the precision.
- The level of nesting of the models can be minimized by including only significant variance contributions larger than 20% of the total variation, which will tighten the upper confidence bound of the precision as the level of nesting decreases.
- Four models each have been developed both for a complete intermediate precision study, and using injection precision from an independent source.
- An Excel spreadsheet that performs all the calculations in this paper as well as the appropriate model selection is available from the authors.
- For a statistical evaluation of the precision of the reportable value, the authors recommend a minimum of six runs, two preparations per run, and two injections per preparation, in order to provide sufficient precision of the variance estimates.

Download English Version:

<https://daneshyari.com/en/article/10154510>

Download Persian Version:

<https://daneshyari.com/article/10154510>

[Daneshyari.com](https://daneshyari.com)