

Title: Validation of Analytical Methods for Pharmaceutical Analysis

Author: Oona McPolin

ISBN: 978-0-9561528-1-7

Publisher: Mourne Training Services

## Errata

	<b>Reads...</b>	<b>Should read...</b>
Page 44, line 24	In this situation part <b>(b)</b> may be combined with the study of other validation characteristics such as accuracy and linearity.	In this situation part <b>(a)</b> may be combined with the study of other validation characteristics such as accuracy and linearity.
Page 78, line 13	If linear regression is performed using the values of actual concentration versus the estimated amount then acceptance criteria may be based on the slope and the intercept, e.g. slope is within 0.98 to 1.02 and the 95% confidence interval includes <b>1</b> for an assay method and slope is within 0.9 to 1.1 and the 95% confidence interval includes <b>1</b> for an impurity method.	If linear regression is performed using the values of actual concentration versus the estimated amount then acceptance criteria may be based on the slope and the intercept, e.g. slope is within 0.98 to 1.02 and the 95% confidence interval <b>of the intercept</b> includes <b>zero</b> for an assay method, and slope is within 0.9 to 1.1 and the 95% confidence interval <b>of the intercept includes zero</b> for an impurity method.
Page 97, Table 19 <i>Rows: Accuracy – Assay &amp; Accuracy – DP 1, Column: Acceptance criteria</i>	95% confidence interval of <b>slope</b> includes <b>1</b>	95% confidence interval of <b>intercept</b> includes <b>zero</b>
Page 120, Table 25 <i>Rows: Accuracy – Assay &amp; Accuracy – DP 1, Column: Acceptance criteria</i>	95% confidence interval of <b>slope</b> includes <b>1</b>	95% confidence interval of <b>intercept</b> includes <b>zero</b>