

3. VALIDATION OF ANALYTICAL PROCEDURES [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Analytical validation information, including experimental data for the analytical procedures listed in 3.2.S.4.2., should be provided.

Reference ICH guidances Q2A, Q2B, and Q6B.

Note to the Author: Please replace the text contained within <<double angle brackets>> with hyperlinks to attachments applicable to this submission.

Validation information demonstrating that the analytical procedures provided in 3.2.S.4.2 and used to test drug substance are suitable for their intended purpose is provided in this section. Validation information for each analytical method included in 3.2.S.4.2 for which validation is required is provided in the following order.

Table 1: Validation reports for Analytical methods used to release {Drug Substance Name}

Test	Analytical Method	Attachment
		<<Validation Report>>
		<<Validation Report>>
		<<Validation Report>>