2. METHODS VALIDATION PACKAGE

Within each Drug Substance and Drug Product section where specifications are required method and validation report can also be included. Since no separate field copy is created with an electronic submission, the need for a standalone Methods Validation package with electronic submissions has become antiquated. We, therefore, suggest that the methods and validation documents live in the appropriate 3.2.P and 3.2.S sections.

With that model, the Methods validation document contained in this section serves as an overview of where the various methods and validation reports exist to aid the chemistry reviewer. For paper submissions, copies of the methods and validation reports should exist here with references from product and substance to this document.

2.1. Drug Substance Methods and Validations

A short TOC listing the various substances that may be a part of this submission should be included here. Each entry of the TOC would reference a table like the sample that follows.

Substance	**Test Methods And Specifications Table**	**COA**

The table above will allow for electronic hyperlinking between this list and the Table that follows as well as to any COAs that may be included with the submission.

2.1.1. {Drug Substance Name} Test Methods and Specifications

Product Attribute	Method	Specification	Testing Facility	Validation	
				Method	Report
Appearance	Physical Inspection	Report data	Company	MTH-00-001	REP-00-001

Note: The 1st line in the table is to serve as an example of how data might be entered in this table. The two columns on the right should be authored in blue text, as these will get hyperlinked to the actual methods and validation reports as submitted. If methods or reports are not submitted then language to the effect or "available upon inspection" could be incorporated as per company culture.

2.2. {Drug Product Name} Test Methods and Specifications

Product Attribute	Method	Specification	Testing Facility	Validation	
				Method	Report
Appearance	Physical Inspection	Report data	Company	MTH-00-001	REP-00-001

2.3. {DRUG PRODUCT NAME} CERTIFICATE OF ANALYSIS

Product Description	Drug Product Lot Number	API Lot Number	Date Of Manufacture

2.4. Drug Product Method Development and Validation Summary

The methods development history and validation studies for the drug product test methods are discussed in this section.

2.5. Summary of Structurally Related Impurities

Any potential impurities structurally related to the drug product as well as potential degradation products are described in this section in the context of how these are tested for and the validations of these methods as appropriate.

2.6. Samples

Samples Are Available Upon Request

This section identifies the samples that will be available for validation of the regulatory methods in FDA laboratories. Typically a statement of "Samples will be provided upon request" is included here. If no samples were being submitted at this time the sections 3.6.1 to 3.6.4 would not be used.

2.6.1. Drug Substance Samples

Note: If no samples were being submitted at this time the sections 3.6.1 to 3.6.4 would not be used.

Tabular list of drug substance samples submitted, including lot number, identity (with chemical name and structure where required for clarity), specifications, package type and size, date of

manufacture, and quantity of the samples. Brief description of special handling (MSDS Sheet) or storage requirements, COA, lot numbering information, and label information should also be attached.

2.6.2. Drug Product Samples

Note: If no samples were being submitted at this time the sections 3.6.1 to 3.6.4 would not be used.

Tabular list of drug product samples submitted, including lot number, composition, specifications, package type and size, date of manufacture, and quantity of the samples. Brief description of special handling (MSDS Sheet) or storage requirements, COA, lot numbering information, and label information should also be attached.

2.6.3. Reference Standards

Note: If no samples were being submitted at this time the sections 3.6.1 to 3.6.4 would not be used.

Description of reference standards that are being sent including special handling requirements, etc, should be described here. A Certificate of Analysis (COA) as well as characterization data should be provided for reference standards that are from non-official sources. Characterization information should include; manufacture information, legible release spectra and instrument data, purity data, chemical attribute data, physical description, and detailed description of analytical procedures used to characterize the reference standard.

2.6.4. Assay controls discussion

Note: If no samples were being submitted at this time the sections 3.6.1 to 3.6.4 would not be used.

Description of assay controls that are being sent including special handling requirements, etc, should be described here.