

2.3.S.5. REFERENCE STANDARDS OR MATERIALS – PREPARATION AND CHARACTERIZATION OF REFERENCE MATERIAL

A summary of the drug substance reference material is presented in Table 2.3.S.5-1. Currently, working reference material (WRM), 20Y513C701-WRM, is used for release and stability testing. Prior to the establishment of the initial WRM, a CRM lot 20Y513C201-RM (established in September 2020) and a development batch of material (lot 00709054-0162-M01) have been used as a reference material/control. The initial development material was used during method development/validation and early release testing of the initial emergency supply materials until CRM lot 20Y513C201-RM was available for use.

A two-tiered system for in-house reference material was implemented to support the commercial product. Primary reference material (PRM), lot 20Y513C701-PRM, is intended to last throughout the commercial product lifetime and will be used for qualification of future working reference materials (WRM). PRM is not intended to be used in routine testing.

An initial WRM, lot 20Y513C701-WRM, was made from the same drug substance batch used to make the PRM and is used to support routine testing of commercial drug substance and drug product until it is consumed and replaced.

Table 2.3.S.5-1. Summary of Reference Materials

Reference Material Designation	Parental Drug Substance Batch	Reference Material Establishment Date	Types of Material Released/Evaluated
Initial Reference Material lot 00709054-0162-M01	00709054-0162-M01	May 2020	Clinical Supplies, Initial Emergency Supplies
Clinical Reference Material lot 20Y513C201-RM	20Y513C201	September 2020	Clinical Supplies Process Validation, Emergency Supplies, Initial Global Commercial Supplies
Primary Reference Material lot 20Y513C701-PRM	20Y513C701	December 2020	Working Reference Material
Working Reference Material Lot 20Y513C701-WRM	20Y513C701	December 2020	Emergency Supplies, Commercial Supplies,

NA = Not Applicable

[Section 3.2.S.5 Reference Standards or Materials - Protocol for Qualification of Future Reference Materials](#) summarizes a protocol for establishment of a future reference material.