

3.2.P.5.3 Validation of Analytical Procedures {Appearance}

The verification of each compendial method is in accordance with Current USP <1226> Verification of Compendial Procedures, such that this report documents evidence of suitability under actual conditions of use. Each compendial method has been assessed as appropriate to the complexity of the procedure.

The compendial test methods have been assessed for suitability using representative sample types and deemed appropriate for testing mRNA-1273 Drug Product as summarized in the [Table 1](#).

Table 1: Summary of Compendial Analytical Test Methods for mRNA-1273 Drug Product

Compendial Test Method	SOP #	Method Verification Report
Appearance	SOP-0278	QC-MVR-0001
		MQR-0310

The compendial test method described in [Table 1](#) has been found to be suitable for the testing of mRNA-1273 Drug Product samples and successfully transferred from the ModernaTX, Inc. QC laboratory in Norwood, MA to the ModernaTX, Inc. QC Laboratory in Dedham, MA.

[QC-MVR-0001](#), attached in this section, provides the method description of each compendial test method, the SOP reference, the compendial reference, the critical materials and equipment to ensure compendia suitability and the evidence of suitability under actual conditions of use and [MQR-0310](#), attached in this section, provides details of the method transfer validation.