

3.2.P.5.3 Validation of Analytical Procedures {Particulate Matter}

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 method has 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
Particulate Matter	SOP-0509	QC-MVR-0001

The compendial test method for Particulate matter has been found to be suitable for the testing of mRNA-1273 Drug Product samples. [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.