

**QUERY 1**

Please provide the established (b) (4) and polydispersity index limits for the control lot of PF-07302048-DP-RM for the test of “Size and polydispersity Index Measurement in mRNA LNP Samples by Dynamic Light Scattering” for drug product.

**RESPONSE 1**

**Table 1** provides the established (b) (4) and maximum polydispersity index (PDI) for control lot PF-07302048-DP-RM.

**Table 1. Established Acceptable (b) (4) and PDI Ranges for PF-07302048-DP-RM (Lot # EE8493)**

Control Criterion	Upper Limit	Lower Limit
(b) (4)		

**Literature References**

None

**SUPPORTING DOCUMENTATION**

**New or Replaced Supporting Documentation**

None

**Previously submitted supporting documentation**

None

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