LRP TEMPLATE FOR STN 125742/0:

QUERY 1:

The lot release protocols previously submitted in amendments 125742/0.4 (dated May 24, 2021) and 125742/0.10 (dated July 9, 2021) need to be modified to be templates for use for all lots submitted to CBER. Lot release templates should be a preset format that does not state results.

Please submit a lot release protocol template (no results stated) for the COVID-19 mRNA Vaccine for CBER review containing only the assays performed and acceptance criteria for the drug product.

The header on each page of the template should state the following:

cc: 000000 _0/Lic #/FC Page 1 of total # of pages
Lot Number:
License Name of Product:

Please note; upon CBER review of the lot release protocol template, additional information may be requested.

RESPONSE 1

A templated lot release protocol (LRP) is provided. Requested information is located at the top of each page. Please note page numbers are in the footer.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

Lot Release Protocol

Previously submitted supporting documentation

Lot Release Documentation Package

QUERY 2

We received three different lots of drug substance (DS) on July 09, 2021 to conduct testing at CBER. You provided one tube of frozen DS for each lot. Please provide instructions for thawing and any other conditions that we need to consider in making aliquots. Also, please state how many freeze-thaw cycles are acceptable. We would appreciate this response as soon as possible, but no later than July 20, 2021.

RESPONSE 2

Thaw DS samples at (b) (4) °C and invert gently to mix. Avoid vigorous mixing.

To avoid multiple freeze-thaws, it is recommended to thaw and aliquot material into single-use sterile polypropylene vials stored at (b) (4) °C. Data to support up to (b) (4) freeze/thaw cycles were studied in studies and can be found documented in 3.2.S.7.3 Stability Data.

Note that clinical, primary, and working reference materials are stored in single-use polypropylene vials as noted in 3.2.S.5 Reference Standards or Materials.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

3.2.S.5 Reference Standards or Materials

3.2.S.7.3 Stability Data