

To: STN 125742/0

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Applicant: BioNTech

Product: COMIRNATY (COVID-19 mRNA Vaccine)

Subject: Test results of lipid nanoparticle size and polydispersity index for COMIRNATY drug product

The determination of COMIRNATY drug product (DP) lipid nanoparticle size and polydispersity index (PDI) was performed on August 17, 2021 per (b) (4)

(b) (4)

(b) (4)

(b) (4)

(a DP lot) were prepared at (b) (4)

DP samples from three lots and the assay control

The test results obtained by DBSQC and those from the firm are summarized in the tables below.

Determination of size

Lot	CBER size (nm)	CBER RSD	Firm size (nm)
Control	(b) (4)		
FC3181			
FC3184			
FD0809			

Determination of PDI

Lot	CBER PDI	Firm PDI
Control	(b) (4)	
FC3181		
FC3184		
FD0809		

The average size of the standard (b) (4) measured by DBSQC was (b) (4) with RSD of (b) (4), meeting the acceptance criteria of (b) (4) respectively. The RSDs for the control and samples both met the same acceptance criteria of (b) (4)

The proposed DP specifications are (b) (4) for (b) (4) and (b) (4) for PDI. CBER test results are similar to those of the firm and meet these criteria.