



MEMORANDUM

Date: September 23, 2021

From: Anil Choudhary, Ph.D., MBA.
CMC Reviewer
Laboratory of Biochemistry, Virology and Immunochemistry (LBVI)
Division of Biological Standards and Quality Control (DBSQC)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: Biologics License Application Submission Tracking Number # 125742/0

Subject: Total RNA content determination for COMIRNATY[®] final container lots for BLA In-Support Testing.

Through: Muhammad Shahabuddin, Ph.D., Lab Chief, LBVI, DBSQC/OCBQ/CBER
Maryna Eichelberger, Ph.D., Director, DBSQC/OCBQ/CBER
Mary A. Malarkey, Director, OCBQ/CBER

Cc: Laura Gottschalk, Ph.D., BLA Review Committee, DVRPA/OVRR
Michael Smith, Ph.D., BLA Review Committee, DVRPA/OVRR
Ramachandra Naik, Ph.D., Chair, BLA Review Committee, DVRPA/OVRR

Applicant: BioNTech

Product: COMIRNATY[®], COVID-19 mRNA Vaccine

Summary:

BioNTech submitted three lots of COMIRNATY[®] vaccine for in-support testing to determine the total RNA content of drug product (DP). The DP lots- FC3181, FC3184 and FD0809 met the total RNA specifications.

Test Results

The total RNA content of COMIRNATY[®], COVID-19 mRNA Vaccine (three DP lots- FC3181, FC3184 and FD0809) was determined using the manufacturer’s procedure for the fluorescence assay. This procedure is described in sponsor’s Test Method # 00-08940A-00 entitled: Quantification of total and percent encapsulated RNA in PF-07302048 by fluorescence using (b) (4). The tests were performed in LBVI, DBSQC, OCBQ. Results from these tests are listed in Tables 1 below:

Table 1: Total RNA content results for three DP lots performed at DBSQC, CBER

Date	Lot#	Total RNA (mg/mL) (DBSQC)	Percent RNA Encapsulation (DBSQC)	Sponsor Results Total RNA mg/mL	Sponsor Results Percent RNA Encapsulation	*Pass/Fail
9/15/2021	FC3181	(b) (4)				Pass
9/15/2021	FC3184					Pass
9/15/2021	FD0809					Pass

*Specification for DP lot: Total RNA= (b) (4) mg/mL and Percent Encapsulation= (b) (4) %

Conclusions

The test results obtained at LBVI, DBSQC, CBER for these COMIRNATY[®] Final Container DP lots demonstrate that lots FC3181, FC3184 and FD0809, met the specifications for Total RNA content. The assay met the system suitability criteria for R² value for the reference standard (Lot# (b) (4)) of (b) (4)