

## BULLET BACKGROUND PAPER

ON

### PFIZER-BIONTECH COVID-19 VACCINE BUFFER SOLUTION

#### PURPOSE

Summarize the types of buffer solution used in Pfizer-BioNTech COVID-19 vaccines as of 8 Nov 21.

#### BACKGROUND

Buffer solutions are used in vaccines to help stabilize proteins by providing adequate solubility and optimal pH. Additionally, by holding the pH and salt levels of the vaccine close to that of our bodies, the injection will be more comfortable when administered.<sup>1</sup>

#### DISCUSSION

- The Pfizer-BioNTech COVID-19 vaccine that was originally approved for Emergency Use Authorization (EUA) in December 2020 and received Biologics License Application (BLA) in August 2021 under the tradename COMIRNATY uses the buffer solution phosphate buffered saline (PBS). This multiple dose vial vaccine has a purple cap and purple border on the vial.<sup>2</sup>
- Because the vaccines manufactured under the EUA and BLA contain the same formulation, doses distributed under the EUA can be used interchangeably with doses licensed under the BLA without safety or effectiveness concerns. The distinction between COMIRNATY and the Pfizer-BioNTech COVID-19 vaccine is legal rather than scientific.<sup>3</sup>
- The Food and Drug Administration (FDA) granted EUA to two new Pfizer-BioNTech COVID-19 vaccine products on 29 Oct 21. Both of these products use tromethamine (Tris) buffer instead of PBS:<sup>4</sup>
  - Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age (10 mcg per dose) with an orange cap and orange border on the vial; and
  - Pfizer-BioNTech COVID-19 vaccine for ages 12 years and above (30 mcg per dose) with a gray cap and gray border on the vial.
- The Pfizer-BioNTech COVID-19 vaccine formulations that use Tris or PBS buffers authorized for use in individuals 12 years of age and older contain the same quantities of mRNA and lipids and differ only with respect to these buffers.
- Accordingly, under the FDA EUA, for individuals 12 years of age and older, COMIRNATY and Pfizer-BioNTech COVID-19 vaccine with either PBS or Tris buffers, when prepared according to their

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<sup>1</sup> <https://www.europeanpharmaceuticalreview.com/article/13699/breaking-old-habits-moving-away-from-commonly-used-buffers-in-pharmaceuticals/>

<sup>2</sup> FDA, "FDA Approves First COVID-19 Vaccine." See also FDA, Approval Letter to BioNTech Manufacturing

<sup>3</sup> <https://crsreports.congress.gov/product/pdf/R/R46913>

<sup>4</sup> <https://www.fda.gov/media/150386/download>

respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns.<sup>2</sup>

- The Tris buffer solution allows for a longer storage of Pfizer-BioNTech mRNA vaccines in refrigerator (2°C to 8°C) status (10 weeks compared to 4 weeks).<sup>5</sup>

- Additionally, Tris buffer solution is used in the Moderna COVID-19 vaccine.<sup>6</sup>

## CONCLUSION

A change to Tris buffer in the Pfizer-BioNTech COVID-19 vaccines allows longer storage in standard refrigerator (2°C to 8°C). All Pfizer-BioNTech COVID-19 vaccines approved either under FDA BLA or EUA can be used interchangeably.

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<sup>5</sup> <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf>

<sup>6</sup> <https://www.fda.gov/media/144636/download>