Paul,

The review team provided me the below response to your e-mail:

The proven acceptance range (PAR) of 0-35 minutes for the is acceptable. Meanwhile, we acknowledge that a target range of will remain in the Andover batch records for both manufacturing sites. Regards,

Mike

Mike,

Regarding the comments on we would ask the review team to consider the relevant supporting information provided in 3.2.S.2.6 Manufacturing Process Development-Process Development and Characterization of the BLA. We have provided relevant information from that document below.

The was studied as an experiment with a range of. The study design and results are described 3.2.S.2.6.
Manufacturing Process Development—Process Development and Characterization and the results are shown in the table below copied from the BLA.

Please confirm receipt of this email. I am available to discuss this issue further with you or members of the review team in order to reach quick resolution.

Regards,

Paul Rohlfing
Executive Director GCMC Vaccines
Pfizer
Elisa,

The review team has the below questions on the drug substance and they have requested a response as soon as possible and no later than COB Wednesday, August 18, 2021.

1. In your drug substance (DS) manufacturing process validation studies performed at both Pfizer and Pfizer the process parameter for the was validated to be within the range of. However, in your documents Section 3.2.S.2.2 Manufacturing Process, the is described as. Please align the acceptance range of this process control parameter in all the documents based on your validation study results.

2. Please update the Tables 3.2.P.3.4-1 in Sections 3.2.P.3.4 Process Step – Puurs and Kalamazoo, to include the validated for DS using both the based on your qualification/validation.
data submitted to BLA 125742 amendment 33 in response to our August 3, 2021 Information Request query 4.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS
Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
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