

QUERY 1

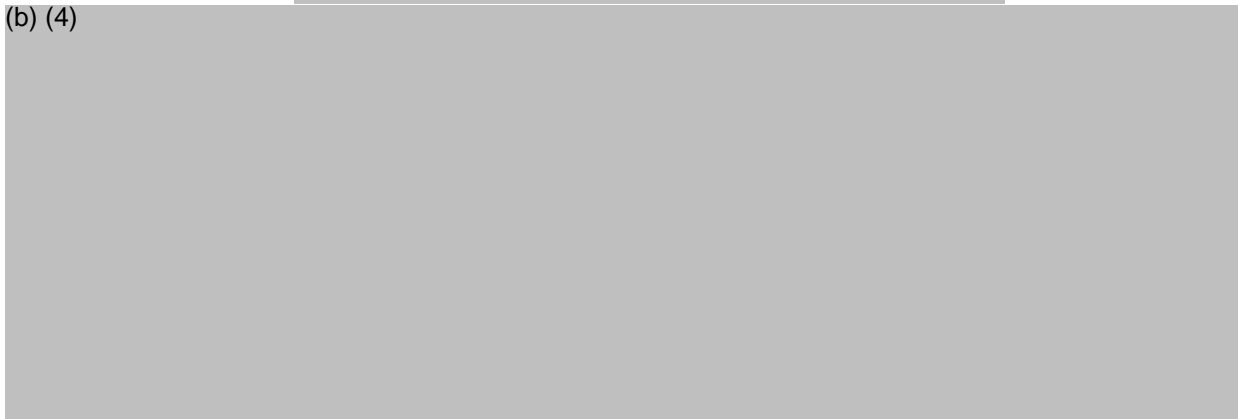
In your drug substance (DS) manufacturing process validation studies performed at both Pfizer (b) (4) and Pfizer (b) (4) the process parameter for the (b) (4) was validated to be within the range of (b) (4). However, in your documents Section 3.2.S.2.2 Manufacturing Process Andover and Section 3.2.S.2.4 Controls of Critical Steps and Intermediates - Manufacturing Process, the (b) (4) is described as (b) (4). Please align the acceptance range of this process control parameter in all the documents based on your validation study results.

RESPONSE 1

The (b) (4) was studied as (b) (4) with a range of (b) (4). The study design and results are described in [3.2.S.2.6 Manufacturing Process Development-Process Development and Characterization](#) and Table 3.2.S.2.6-11 has been copied below. The full range of the study gave acceptable results, with no trends noted.
(b) (4)

Table 3.2.S.2.6-11. (b) (4) Study Results

(b) (4)



Data in the study was compared with original specifications. The commercial acceptance criteria for (b) (4) specification have been updated to (b) (4) respectively, but this does not change the conclusion of the study.

(b) (4)



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Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

3.2.S.2.6 Manufacturing Process Development-Process Development and Characterization

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QUERY 2

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

RESPONSE 2

Validated (b) (4) for drug substance (b) (4) using (b) (4), were added to Tables 3.2.P.3.4-1 of [Section 3.2.P.3.4 Process Step \(b\) \(4\) – \(b\) \(4\)](#) [Puurs] and [Section 3.2.P.3.4 Process Step \(b\) \(4\) – \(b\) \(4\)](#) [Kalamazoo].

Table 3.2.P.3.3-1, Table 3.2.P.3.3-2 and Table 3.2.P.3.3-19 in [Section 3.2.P.3.3 \(b\) \(4\)](#) [Puurs] and [Section 3.2.P.3.3 \(b\) \(4\)](#) [Kalamazoo] were also updated to reflect the validated (b) (4) for drug substance (b) (4).

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

Section 3.2.P.3.3 (b) (4) [Puurs], replaced

Section 3.2.P.3.3 (b) (4) [Kalamazoo], replaced

Section 3.2.P.3.4 Process Step (b) (4) – (b) (4) [Puurs], replaced

Section 3.2.P.3.4 Process Step (b) (4) – (b) (4) [Kalamazoo], replaced

Previously submitted supporting documentation

None