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QUERY 1

In Section 3.2.S.2.5 Process Validation and/or Evaluation – Shipping Performance Qualification, you stated that the expected transit time for shipment of the (b) (4) DS from the Pfizer Andover DS manufacturing site to the Pfizer Kalamazoo and Pfizer Puurs DP manufacturing sites is (b) (4), respectively. Please provide supportive data to demonstrate that the physicochemical and biological attributes of the DS are not impacted after exposure to the shipping hazards (e.g., shock, vibration, pressure, thermal hazards, etc.). Please note that the data should be able to support the worst-case transit time of (b) (4) (b) (4) DS.

RESPONSE 1

(b) (4)



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(b) (4)



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(b) (4)



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Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

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QUERY 2

Please update the Table 3.2.S.2.5-2 “Performance Tests for Commercial Scale (b) (4) Validation and Routine Batches” in Section 3.2.S.2.5 Process Validation and/or Evaluation – Additional Process Evaluation to include the acceptance criteria/action limit for the (b) (4) performance-related parameters based on the results from the initial validation studies and the experience from commercial production.

RESPONSE 2

The (b) (4) is monitored for (b) (4) validation using the performance parameters with established acceptance criteria based on initial validation studies and early commercial production as listed in the Table 2 below. Table 3.2.S.2.5-2 in Section 3.2.S.2.5 Process Validation and/or Evaluation-Additional Process Evaluation has been updated.

(b) (4)



Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

[3.2.S.2.5 Process Validation and/or Evaluation – Additional Process Evaluation](#) Replaced

Previously submitted supporting documentation

None

QUERY 3

In document INX100433827: COVID-19 Vaccine Drug Substance Process Validation Final Report, a deviation (PR ID 5222684) described that for PPQ batches 20Y513C301 – 20Y513C601, (b) (4) was set (b) (4). However, in Table 4-5 Results for Additional Process Inputs, (b) (4) rate for all the impacted batches was recorded as (b) (4). Please explain this discrepancy.

RESPONSE 3

(b) (4)



Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

[INX100433827: COVID-19 Vaccine Drug Substance Process Validation Final Report for \(b\) \(4\), Andover, MA](#)

Previously submitted supporting documentation

QUERY 4

Regarding the process validation and/or evaluation for the (b) (4) [redacted] in Pfizer Kalamazoo and Pfizer Puurs, please describe any process controls and performance verification implemented at the DS (b) (4) [redacted] during PPQ execution and provide available data to support the use of both (b) (4) [redacted] (b) (4) [redacted]. Please also confirm that the (b) (4) [redacted] for all evaluated PPQ lots was within the target (b) (4) [redacted].

RESPONSE 4

(b) (4)



(b) (4)



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(b) (4)



(b) (4)



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(b) (4)



Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

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Previously submitted supporting documentation

None

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QUERY 5

Please update the Table 3.2.A.3.1.1-1 Nomenclature of ALC-0315 in Section 3.2.A.3.1.1 Nomenclature [ALC-0315] to include the product number/code for the lipid ALC-0315 manufactured in (b) (4).

RESPONSE 5

(b) (4) does not have a unique product number/code for the ALC-0315 lipid. However on their documentation, they report ALC-0315 as ALC-315. Therefore, Section 3.2.A.3.1.1 Nomenclature [ALC-0315] is updated to indicate that ALC-0315 may be referred to as ALC-315.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

[Section 3.2.A.3.1.1 Nomenclature \[ALC-0315\]](#), Replaced

Previously submitted supporting documentation

None

QUERY 6

Regarding your response (in STN 125742/0.16 dated July 23, 2021) to our IR query 3 dated July 9, 2021, about the validation of the CGE Integrity method, we do not agree that a conclusion of a quantification limit of (b) (4)

(b) (4) The results as shown in Table 3 may infer a quantification limit for (b) (4)

(b) (4) We acknowledge that the assay is not for the assessment of impurity and the actual quantification limit for impurity was not determined.

RESPONSE 6

We acknowledge that the Quantification Limit (QL) of (b) (4) is inferred and the actual QL for (b) (4) was not demonstrated as part of the method validation studies. (b) (4) was provided as part of the method validation for the reportable of (b) (4)(b) (4)) and the method has been demonstrated to be suitable for intended use.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

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