

QUERY 1

Please describe the spiked materials used for evaluating the

(b) (4)



RESPONSE 1

(b) (4)

(b) (4)

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(b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

[VAL100136603](#), REPORT FOR THE VALIDATION OF THE METHOD TM100010392;
RNA INTEGRITY OF MRNA DRUG SUBSTANCE AND LNP-MRNA DRUG
PRODUCT SAMPLES BY FRAGMENT ANALYZER (CGE)

090177e1979cc629\Approved\Approved On: 21-Jul-2021 16:20 (GMT)

QUERY 2

The acceptance criterion for the assay Range evaluation is stated as (b) (4)

[Redacted]

(b) (4) Please comment and provide additional data to support your proposed acceptance criterion for the RNA integrity Range evaluation.

RESPONSE 2

(b) (4)

(b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

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RNA INTEGRITY OF MRNA DRUG SUBSTANCE AND LNP-MRNA DRUG
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QUERY 3

You stated on Page 31 that the assay quantitation limit (QL) was determined from the results

(b) (4)

(b) (4)

study. Please explain.

RESPONSE 3

(b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

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