QUERY 1

Regarding the (b) (4) sterility method:

a. Please confirm that both PGS-Puurs and PGS-KZO testing facilities will conduct (b) (4) (b) (4) of (b) (4) sterility tests since test results for (b) (4) were not optimal during the validation study.

b. Please confirm that both PGS-Puurs and PGS-KZO testing facilities will conduct visual inspection for growth during the (b) (4) .

RESPONSE 1

a. The applicant confirms that a (b) (4) is used at both PGS-Puurs and PGS-KZO.

b. The applicant confirms that both PGS-Puurs and PGS-KZO testing facilities conduct visual inspection for growth during the (b) (4) (b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

QUERY 2

Regarding the endotoxin test:

a. Please submit complete verification reports of the endotoxin tests for interfering factors from both the PGS-Puurs and PGS-KZO facilities. These reports should include positive product control (PPC) percent recoveries for all drug product sample dilutions tested and the selected testing dilution that provided the optimal PPC percent recovery. In addition, the reports should identify the product lot numbers tested instead of referring to them as Trials 1, 2 and 3, as in the submitted summarized verification of bacterial endotoxins report.

RESPONSE 2

Complete verification reports are included for both PGS-Puurs and PGS- KZO.

For Puurs, the most current version of the endotoxin verification report also covers endotoxin testing for (b) (4) (b) (4)
(b) (4)

(b) (4)

(b) (4) In addition, the report identifies the product lot numbers hem as Trials 1, 2 and 3, as in the submitted summarized verification of bacterial endotoxins report.

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

Kalamazoo (b) (4) Method Verification Report.pdf

LAL-20-018-A8_PUURS.pdf

Previously submitted supporting documentation

None