## CERTIFICATE OF ANALYSIS

PRODUCT:

10 ml 100 ± 4 ppb Oxytetracycline Standard

LOT NUMBER:

OT10-015

**EXPIRATION DATE: May 2020** 

ORDER CODE:

OT100, OT100-5

DESCRIPTION:

10 ml 100  $\pm$  4 ppb Oxytetracycline Standard contains 1.00  $\pm$ 0.03 µg freeze dried oxytetracycline manufactured from official U. S. Pharmacopeia (USP) reference standard catalog 1491004

using analytical chemistry techniques.

HPLC analysis determines that the production stock solution purity and concentration are within 6% of a fresh oxytetracycline standard solution made directly

from official USP reference standard.

Finished product quality control approval is based on the Charm II Tetracycline Test and ROSA Tetracycline Test. The specification for acceptance is within 10% for Charm II and within 20% for ROSA of a master control standard or freshly made standard from USP reference standards. Shelf life studies, heat stress studies and frozen stability studies are performed to verify operator's manual claims.

PREPARATION:

See operator's manual.

STORAGE:

See operator's manual.

PREPARED BY:

Sam Atoui

SIGNATURE:

TITLE:

Quality Assurance Documentation Manager

DATE:

12/14/2018