

CERTIFICATE OF ANALYSIS

PRODUCT:

100 ml 0.0080 ± 0.0002 IU/ml Penicillin G Standard /

80 ml 0.0100 ± 0.0003 IU/ml Penicillin G Standard

LOT NUMBER:

30332A

EXPIRATION DATE:

September 2022

ORDER CODE:

PG008, PG008-5, PG008-10, PG008-20, PG01, PG01-5

DESCRIPTION:

Contains 0.80 ± 0.01 IU freeze dried penicillin G manufactured from official USP (U. S. Pharmacopeia) reference standard Penicillin G Potassium, catalog number 1502508, using analytical chemistry techniques. HPLC analysis determines that the production stock solution purity and concentration are within 6% of a fresh penicillin G potassium standard solution made directly

from official USP Reference Standard.

Finished product quality control approval is based on Charm II Beta-lactam Test and *B.stearothermophilus*Disc Assay testing within acceptable variation from a master control standard or a freshly made standard from

USP Reference Standard Penicillin G Potassium.

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:

09/03/2020