# **Certificate of Quality**

Product Name: Charm MRL Beta-lactam 3 Minutes Test

Lot Number: MRLBL3-014C

Expiration Date: December 2024

Order Codes: LF-MRLBL3, LF-MRLBL3P

This product was quality tested and met Charm Sciences' quality control criteria for release for sale including performance and appearance specifications.

Name: Michael T. Wade

Title: Document Control Manager

Date: 03/14/2024

### **TYPICAL COUNTS for**

#### **Charm MRL Beta-lactam 3 Minute Test**

See Operator's Manual for use and application.

Kit Code: LF-MRLBL3

Lot Number: MRLBL3-014C

#### Charm ROSA Reader

<b>Negative Control</b>	-1313	2356	4.2 ppb Penicillin G
	-1691	2427	<b>Tablet Positive Control</b>
	-2229	2066	
	-1565	2754	
	-1755	2387	
	-1566	2092	
	-1793	2123	
	-1630	2375	
	-1868	2005	
	-1200	2068	

Note: Typical counts are provided as a performance guide only.

Operators' daily control numbers may be compared to the supplied information as an operator, equipment and analyzer calibration check. Daily control data should typically test in the range of data points provided.

The control point for the MRL Beta-lactam 3 minute test is always zero.

## **CERTIFICATE OF ANALYSIS**

PRODUCT: Penicillin G Positive Tablet

 $(5.0 \text{ ml}, 5.0 \pm 0.5 \text{ ppb or } 6.25 \text{ ml}, 4.0 \pm 0.4 \text{ ppb})$ 

LOT NUMBER: STDP-025

**EXPIRATION DATE: February 2025** 

ORDER CODE: LF-PG5-TBL

DESCRIPTION: Contains 25.0 ± 2.5 ng freeze dried Penicillin G

manufactured from official USP (U. S. Pharmacopeia) Reference Standard Penicillin G Potassium, catalog

number 50250.

Finished product quality control approval is based on Charm II Beta-lactam Test, Charm SL Beta-lactam Test

and Charm MRL Beta-lactam Test testing within

acceptable variation from a master control standard or 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.

PREPARED BY: Michael T. Wade

SIGNATURE:

TITLE: Document Control Manager

DATE: 01/04/2024