IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 10874.1

Drug Product: Phenylephrine 1000 mcg/10 mL, Syringe for Injection

Batch/Lot ID: **20211229PHE-3** NDC: 71139-7084-1

Strength: 1000 mcg Container: 10 mL syringe Volume (Amount): 10 mL

Production Date: 12/29/2021 Expiration Date: 06/27/2022

Storage: Room Temperature, 20ºC - 25ºC

Testing Results

Test/Parameter	***Specification***	***Result***	***Date of Analysis***
Phenylephrine HCl Potency / ID	90.0 % - 115.0 % / Positive	101.9 % / Positive	01/10/2022
Endotoxin (USP <85>)	≤ 2.50 EU/mL	< 0.050 EU/mL	01/07/2022
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	01/20/2022
Visual Inspection	NMT 0 Units Non-Conforming	Pass	12/29/2021
Filter Integrity	Pressure > 55 psi	NA	NA

*Comments: CofA updated with final sterility results. KD 01/20/2022

Statement of Conformity:

IntegraDose Compounding Services, LLC certifies that the above product has successfully passed all testing as per the applicable test specifications. All products manufactured under IntegraDose's Quality System meet the regulatory requirements for 503B Outsourcing Facilities (21 USC 353b: Outsourcing facilities and the FDA Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act) and all other applicable internal Quality requirements. All products are manufactured with validated processes to current specifications and are inspected to ensure they meet quality requirements.

Certificate Preparation Date: 01/20/2022 By/Date: Kelly Dewitz Digitally signed by Kelly Dewitz Date: 2022.01.20 15:55:33 -06'00'

Quality Review/Date: _____