



IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 10820

Drug Product: Phenylephrine 1000 mcg/10 mL, Syringe for Injection			
Batch/Lot ID: 20211122PHE-3		NDC: 71139-7084-1	
Strength: <u>1000 mcg</u>	Container: <u>10 mL syringe</u>	Volume (Amount): <u>10 mL</u>	
Production Date: <u>11/22/2021</u>		Expiration Date: <u>05/21/2022</u>	
Storage: Room Temperature, 20°C - 25°C			
Testing Results			
<i>Test/Parameter</i>	<i>Specification</i>	<i>Result</i>	<i>Date of Analysis</i>
Phenylephrine HCl Potency / ID	90.0 % - 115.0 % / Positive	98.2 % / Positive	11/30/2021
Endotoxin (USP <85>)	≤ 2.50 EU/mL	< 0.050 EU/mL	12/02/2021
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	12/13/2021*
Visual Inspection	NMT 0 Units Non-Conforming	Pass	11/22/2021
Filter Integrity	Pressure > 55 psi	NA	NA
*Comments: Confirmed batch on test - no turbidity to date. Final results are pending a 14 day read.			
Statement of Conformity: <i>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.</i>			

Certificate Preparation Date: 12/13/2021 By/Date: _____

Quality Review/Date: _____

719 Kasota Ave Southeast, Minneapolis, MN 55414

integradoses.org

