



# Certificate of Manufacture / Analysis

Certificate ID: 10899

Drug Product: Phenylephrine 1000 mcg/10 mL, Syringe for Injection			
Batch/Lot ID: 20220110PHE-3		NDC: 71139-7084-1	
Strength: 1000 mcg Container: 10 mL syringe Volume (Amount): 10 mL			
Production Date: 01/10/2022		Expiration Date: 07/09/2022	
Storage: Room Temperature, 20°C - 25°C			
Testing Results			
Test/Parameter	Specification	Result	Date of Analysis
Phenylephrine HCl Potency / ID	90.0 % - 115.0 % / Positive	99.9 % / Positive	01/14/2022
Endotoxin (USP <85>)	≤ 2.50 EU/mL	< 0.050 EU/mL	01/18/2022
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	01/27/2022
Visual Inspection	NMT 0 Units Non-Conforming	Pass	01/10/2022
Filter Integrity	Pressure > 55 psi	NA	NA
*Comments: NA			
<b>Statement of Conformity:</b> 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: 01/31/2022 By/Date: \_\_\_\_\_

Quality Review/Date: \_\_\_\_\_

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