IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 10902

Drug Product: Oxytocin 30 Units/500 mL, Bag for Injection

Batch/Lot ID: **20220124OXY-3** NDC: 71139-0012-1

Strength: 30 units Container: 500 mL bag Volume (Amount): 503 mL

Production Date: 01/24/2022 Expiration Date: 04/24/2022

Storage: Room Temperature, 20ºC - 25ºC

Testing Results

Test/Parameter	***Specification***	***Result***	***Date of Analysis***
Oxytocin Potency / ID	90.0 % - 110.0 % / Positive	101.9 % / Positive	01/28/2022
Endotoxin (USP <85>)	≤ 2.142 EU/mL	< 0.48 EU/mL	01/28/2022
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	02/03/2022*
Visual Inspection	NMT 0 Units Non-Conforming	Pass	01/24/2022
Filter Integrity	Pressure > 55 psi	Pass	01/24/2022

*Comments: Confirmed batch on test - no turbidity to date. Final results are pending a 14 day read.

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: 02/03/2022 By/Date: Kelly Dewitz Digitally signed by Kelly Dewitz Date: 2022.02.03 13:39:00 -06'00'

Quality Review/Date: Natalie J Horton Digitally signed by Natalie J Horton Date: 2022.02.04 08:54:36 -06'00'