



IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 10889

Drug Product: Hydromorphone HCl 20mg/100mL, CADD for Injection			
Batch/Lot ID: 20211228HYD-2		NDC: 71139-0018-1	
Strength: <u>20 mg</u>		Container: <u>100 mL CADD cassette</u>	
Volume (Amount): <u>100 mL</u>		Production Date: <u>12/28/2021</u>	
Expiration Date: <u>04/27/2022</u>		Storage: Room Temperature, 20°C - 25°C	
Testing Results			
Test/Parameter	Specification	Result	Date of Analysis
Hydromorphone HCl Potency / ID	95.0 % - 105.0 % / Positive	101.6 % / Positive	01/26/2022
Endotoxin (USP <85>)	≤ 17.60 EU/mL	< 0.48 EU/mL	01/07/2022
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	01/06/2022
Visual Inspection	NMT 0 Units Non-Conforming	Pass	12/28/2021
Filter Integrity	Pressure > 55 psi	NA	NA
*Comments: NA			
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: 01/27/2022 By/Date: _____

Quality Review/Date: _____

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