



IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 11002

Drug Product: Hydromorphone HCl 20mg/100mL, CADD for Injection			
Batch/Lot ID: 20220222HYD-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>02/22/2022</u>		Expiration Date: <u>06/22/2022</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	100.1 % / Positive	03/03/2022
Endotoxin (USP <85>)	≤ 17.60 EU/mL	<0.48 EU/mL	03/04/2022
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	03/03/2022
Visual Inspection	NMT 0 Units Non-Conforming	Pass	02/22/2022
Filter Integrity	Pressure > 55 psi	Pass	02/22/2022
*Comments: NA			
<u>Statement of Conformity:</u> <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: 03/24/2022

By/Date: _____

Quality Review/Date: _____

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integradose.org

