IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 10771.1

Drug Product: Fentanyl Citrate 2500 mcg/50 mL, CADD for Injection

Batch/Lot ID: **20211028FEN-2** NDC: 71139-6030-1

Strength: 2500 mcg Container: 50 mL CADD cassette Volume (Amount): 50 mL

Production Date: 10/28/2021 Expiration Date: 12/27/2021

Storage: Room Temperature, 20ºC - 25ºC

Testing Results

Test/Parameter	***Specification***	***Result***	***Date of Analysis***
Fentanyl citrate Potency / ID	90.0 % - 110.0 % / Positive	92.7 % / Positive	11/04/2021
Endotoxin (USP <85>)	≤ 2.50 EU/mL	<1.00 EU/mL	11/05/2021
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	11/18/2021
Visual Inspection	NMT 0 Units Non-Conforming	Pass	10/28/2021
Filter Integrity	Pressure > 55 psi	Pass	10/28/2021

*Comments: CofA updated with final sterility results. RMW 11/19/2021

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: 11/19/2021 By/Date: Renee Wright 2021.11.19 10:26:17 -06'00'

Quality Review/Date: Digitally signed by Kimberly A Grandprey Date: 2021.11.23 10:26:22 -06'00'