IntegraDose™
Compounding Services

Certificate of Manufacture / Analysis

Certificate ID: 10812

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

Batch/Lot ID: **20211124FEN-2** NDC: 71139-6030-1

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

Production Date: 11/24/2021 Expiration Date: 01/23/2022

Storage: Room Temperature, 20ºC - 25ºC

Testing Results

Test/Parameter	***Specification***	***Result***	***Date of Analysis***
Fentanyl citrate Potency / ID	90.0 % - 110.0 % / Positive	100.7 % / Positive	12/02/2021
Endotoxin (USP <85>)	≤ 2.50 EU/mL	< 0.25 EU/mL	12/03/2021
Sterility (USP <71>)	Negative Growth (at 14 Days)	Negative	12/07/2021*
Visual Inspection	NMT 0 Units Non-Conforming	Pass	11/24/2021
Filter Integrity	Pressure > 55 psi	Pass	11/24/2021

*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: 12/07/2021 By/Date: Kelly Dewitz Digitally signed by Kelly Dewitz Date: 2021.12.07 14:08:16 -06'00'

Quality Review/Date: Digitally signed by Kimberly A Grandprey Date: 2021.12.09 10:01:47 -06'00'

Preliminary