

# Certificate of Manufacture / Analysis

Certificate ID: 10968

| Drug Product: Cefazolin 2 Gram/20 mL, Syringe for Injection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |                                    |                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------|------------------|
| Batch/Lot ID: <b>20220218CEF-2</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                 | NDC: 71139-7087-1                  |                  |
| Strength: <u>2 gram</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Container: <u>30 mL syringe</u> | Volume (Amount): <u>20 mL</u>      |                  |
| Production Date: <u>02/18/2022</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                 | Expiration Date: <u>04/04/2022</u> |                  |
| Storage: Refrigerated Temperature, 2°C - 8°C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                 |                                    |                  |
| Testing Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                 |                                    |                  |
| Test/Parameter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Specification                   | Result                             | Date of Analysis |
| Cefazolin Potency / ID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 90.0 % - 115.0 % / Positive     | 99.5 % / Positive                  | 03/01/2022       |
| Endotoxin (USP <85>)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | ≤ 15.0 EU/mL                    | 1.95 EU/mL                         | 02/25/2022       |
| Sterility (USP <71>)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Negative Growth (at 14 Days)    | Negative                           | 03/07/2022*      |
| Visual Inspection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | NMT 0 Units Non-Conforming      | Pass                               | 02/18/2022       |
| Filter Integrity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Pressure > 55 psi               | NA                                 | NA               |
| *Comments: Confirmed batch on test - no turbidity to date. Final results are pending a 14 day read.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                 |                                    |                  |
| <p><b>Statement of Conformity:</b></p> <p>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&amp;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.</p> |                                 |                                    |                  |

Certificate Preparation Date: 03/07/2022 By/Date: \_\_\_\_\_

Quality Review/Date: \_\_\_\_\_