Attachment 1: Certificate of Analysis Template

Certificate of Analysis:

CSP: Ephedrine Sulfate PF 5mg/mL; 5mL Syringe

CSP Code:	71546-012-05		
Container/Volume:	5mL Syringe	Storage: Room Temp/Protect from Light	
Lot Code:	20220214-871399	Date Compounded: 14FEB2022	
Beyond Use Date:	14JUL2022		

Ingredients: Each ml contains: Ephedrine Sulfate, USP 5mg (equivalent to 3.8mg ephedrine base); 0.9% Sodium chloride, USP in water for injection; pH is adjusted with Sodium Hydroxide and/or glacial acetic acid if necessary.

Test Results

Method	Specifications	Results
pH	4.5 – 7.0	**4.76**
100% Visual Inspection	Conforms to USP	**Conforms**
Potency / Purity: HPLC	95.0 – 105.5%	**102.0%**
Endotoxin: USP <85>	≤35 EU/mL	**<1 EU/mL**
Sterility: USP <71>	Conforms to USP	**Conforms**
Particulate: USP <788>	Conforms to USP	**Conforms**

The following compounded sterile product has been compounded and packaged by Advanced Compounding Solutions in accordance with current Good Manufacturing Practices; that all documentation pertinent to this batch has been properly reviewed; that the product complies with the pre-set specifications; and that values as stated on the Certificate of Analysis are a true representation of the analytical test results.

***Notes**: N/A

QA Approval

Title: QA ASSOCIATE I **Signature:** Bunrong Kun (Mar 7, 2022 12:13 EST) **Date:** 07-Mar-22

– **CONFIDENTIAL** –

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20220214-871399 Ephedrine Sulfate PF 5mg per mL in 5mL Syringe

Final Audit Report 2022-03-07

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Status:	Signed
Transaction ID:	CBJCHBCAABAA8HFm3-j3tytH0JA32ddswm-qoxYSjWFH

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