

CERTIFICATE OF ANALYSIS

Customer: New England Life Care Storage: Room

Temperature-Light

Protect

Received: 10/03/2018 Device/Amount: syringe(s) 13 x 5 ml

Compound: PHENYLEPHRINE 100MCG/ML IN 0.9% Sample Number: W-1-1243

NACL

Lot Code: 20181001-533C32 DEA: No

RESULTS

Test	Active	Test Spec	Test Result	Test Date	Tech Review Date	Comment
Potency/Purity : HPLC ¹	Phenylephrine HCl	90.0 - 115.0 %	102.4% (102.4 mcg/mL)	10/04/2018	10/10/2018	
Endotoxin : USP <85> ²		≤ 2.50 EU/mL	<0.050 EU/mL	10/09/2018	10/09/2018	
Sterility : USP <71> ³		Negative at 14 days	Negative at 14 days	10/18/2018	10/18/2018	

Compounded By: Yin, Michelle Date Compounded: 10/1/2018

- Meets all USP<1225> validation criteria including stability indicating, specificity to formulation and container closure systems per USP/ICH guidelines for specific customer formulation.
- 2. USP <85> Turbidimetric or Photometric Technique.
- 3. USP <71> Sterility Test. Includes tests for Aerobic and Anaerobic Bacteria, and Fungi (Mold and Yeasts).

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Final QA By: Dalton Hazelett Date: 10/18/2018

Down There