



# Certificate of Analysis

## Sodium Chloride 0.9% (Normal Saline), USP Sterile Grade

Product Number: Z1377  
Product Size: 6 x 1 L

Lot Number: 21304212  
Date of Manufacture: 2021-04-13  
Expiration Date: 2022-10-13  
Storage Temperature: 15 - 30 °C

### BASIS FOR RELEASE

Test	Method	Specification	Result
Appearance	Visual	Clear and Colorless Liquid	Clear and Colorless Liquid
Chloride Identification	USP <191>	Passes Test	Pass
Concentration (w/v)	USP	0.855 - 0.945%	0.906 %
Conductivity (Packaged)	USP	15.0 - 17.6 mS/cm	16.15 mS/cm
Endotoxin	USP <85>	≤ 0.5 EU/mL	< 0.005 EU/mL
Iron	USP <241>	Passes Test	Pass
NaCl	USP	8.55 - 9.45 g/L	9.06 g/L
Particulate Matter	USP <788>	≤ 3 particles per mL that are ≥ 25 µm in size	0.00 particles/mL
Particulate Matter	USP <788>	≤ 25 particles per mL that are ≥ 10 µm in size	0.00 particles/mL
pH	USP <791>	4.5 - 7.0	6.02
Sodium Identification	USP <191>	Passes Test	Pass
Sterility	USP <71>	No Growth	No Growth

This lot has been produced using Current Good Manufacturing Practices (cGMP). The solution meets all requirements for residual solvents USP <467>.

This product is not of animal origin and does not contain, make use of or involve animal components during its manufacturing process.

No antimicrobial or other substance has been added.

### STATEMENT FOR USE

This product is for further manufacturing, laboratory, or research use only.  
Not intended for direct human or veterinary parenteral administration or where prohibited by law.

### Approval

Quality Assurance – Print Name:	Quality Assurance – Sign Name:	Date:
Jessica Hymas		30 Apr 2021