



IrvineScientific®

PRODUCT WFI QUALITY WATER  
For Cell Culture and Further  
Manufacturing Use Only

LOT #XXXXXXXXXX

CATALOG #9309

MFR DATE: 02/05/13

EXPIRES: 02/28/15-1.0L  
02/29/16-20L  
02/29/16-200L

REV 1

PREPARED BY: HHH 03/12/13

STORAGE: 2-30°C

### CERTIFICATE OF ANALYSIS

Products manufactured by Irvine Scientific are produced in accordance with the Guideline for Manufacture of In Vitro Diagnostic Products and the Good Manufacturing Practices (GMP's) for Medical Devices. Irvine Scientific is licensed by both Federal and State agencies and is inspected regularly for compliance. Water meets the testing requirements for Sterile Water for Injection as stated in current USP and EP. It contains no added substances.

Appearance Clear colorless liquid

Cell Culture When used to prepare a complete liquid cell culture medium in accordance with the current manufacturing protocol for specific catalog number grows on Normal Human Fibroblasts (NHF, diploid cell strain), or equivalent. Cells are propagated for three serial passages and carried in parallel with an appropriate control media. Cells are observed for absence of toxicity or cytopathic effects (CPE).

Assay	Specification	Result	Method
Sterility	Pass	Pass	USP <71>, 21CFR610.12, EP (2.6.1)
Endotoxin <sup>1</sup>	<0.25 EU/ml	<0.05 EU/ml	USP <85>, EP (2.6.14)
Conductivity	≤ 5 µS/cm	1.1 µS/cm	USP <645>, EP Sterilized WFI
Oxidizable Substances	Conforms	Conforms	USP/EP Sterile WFI
Acidity or Alkalinity	Conforms	Conforms	EP Sterilized WFI
Chlorides	Conforms	Conforms	EP (2.4.4)
Nitrates	NMT 0.2 ppm	Conforms	EP Sterilized WFI
Sulfates	Conforms	Conforms	EP Sterilized WFI
Aluminium	NMT 10 ppb	Conforms	EP (2.4.17)
Ammonium	NMT 0.2 ppm	Conforms	EP Sterilized WFI
Calcium and Magnesium	Conforms	Conforms	EP Sterilized WFI
Heavy Metals	NMT 0.1ppm	Conforms	EP (2.4.27)
Particulate Matter	Conforms	Conforms	USP <788>, EP (2.9.19)
Residue on Evaporation	NMT 0.003%	Conforms	EP Sterilized WFI

<sup>1</sup>Utilizes a Chromogenic Assay with a sensitivity of 0.05 EU/ml.