

Code No.23-0280

SPECIFICATION

WFI Quality Water

for Cell Culture

REQUIREMENT	SPECIFICATION
* Description (JP)	Clear and colorless liquid, having no odor
Purity (JP)	to pass test
Conductivity (JP)	not more than $5\mu\text{S}\cdot\text{cm}^{-1}$
Bacterial endotoxins (JP)	less than 0.25EU/mL
Foreign insoluble matter (JP)	to pass test
Insoluble particulate matter (JP)	to pass test
Sterility (JP)	to pass test
Total organic carbon (USP-NF)	to pass test
Water conductivity (USP-NF)	to pass test
Particulate matter in injections (USP-NF)	to pass test
Sterility tests (USP-NF)	to pass test
Bacterial endotoxins test (USP-NF)	less than 0.25 USP Endotoxin Units/mL
Conductivity (Ph.Eur.)	maximum $5\mu\text{S}\cdot\text{cm}^{-1}$
Total organic carbon (Ph.Eur.)	to pass test
Residue on evaporation (Ph.Eur.)	maximum 0.003%
Particulate contamination: sub-visible particles (Ph.Eur.)	to pass test
Sterility (Ph.Eur.)	to pass test
Bacterial endotoxins (Ph.Eur.)	less than 0.25IU/mL

(*:Additional test performed by Wako)Japanese Pharmacopoeia (Sterile Water for Injection in Containers)United States Pharmacopeia - National Formulary (Sterile Water for Injection)European Pharmacopoeia (Sterilised water for injections)