

Water for Injection Measurements

BACKGROUND

Water is one of the most widely used raw materials in the pharmaceutical plant. Several grades of water are used throughout the plant. One grade, Water for Injection (WFI), is water purified by reverse osmosis or distillation as specified by the United States Pharmacopeia (USP). Specific tests for Conductivity apply to WFI Water produced on site for manufacturing purposes.

PROCESS

The process starts with raw water conforming to US EPA National Primary Drinking Water Regulations or comparable standards of the European Union or Japan. The water contains no added substances. For Reverse Osmosis systems, the raw water is passed through semi-permeable membrane filtration where the pores in the membrane effectively reject dissolved ions, salts and organic compounds. Filtration units are located before and after the membrane modules, a booster pump to increase net pressure across the membranes, and storage tanks.

For Distillation systems, a phase change from liquid to vapor occurs, enabling the pre-treated feed water to be stripped of any residual ion materials, particulate, colloids and non-volatile organic compounds. Demisters and separation devices remove any material that may be entrenched in the purified vapors. Single effect distillation units consist of a series of columns where the phase change occurs, the evaporation and subsequent condensation being considered a single effect. Multiple effect units may be used depending on the water usage demand. The distillate is gravity fed to a storage tank.

CONDUCTIVITY SOLUTIONS

Water for Injection systems must consistently produce water that is compliant with the latest the USP revision; meaning raw conductivity is measured and compared to the water temperature. Conductivity levels exceeding limits as designated by the USP cannot be classified as WFI Water unless additional tests are performed (refer to table 1). Conductivity sensors must be accurate below 1.3 microSiemen/cm and

must include an accurate temperature measurement. The analyzer must be able to output the raw, uncompensated conductivity value and the temperature.

Preferred material of construction for wetted components is polished and passivated stainless steel to minimize the number of micropores in the metal surfaces, which prevents corrosion or microbial growth. WFI Systems are validated to installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). Component level equipment must include proper documentation to facilitate the validation process. Typically there are two conductivity sensors per system so a percent passage or percent rejection can be determined. Additional conductivity sensors may be placed on storage tank outlets depending on the facility's WFI demand.

INSTRUMENTATION SOLUTION

The Rosemount Analytical Model 403 Endurance Conductivity Sensor with either the Solucomp Model Xmt or Solucomp II Model 1056 is the conductivity solution for the Water for Injection System.

The Model 403 Conductivity Sensor accurately measures conductivity below 1 microSiemen/cm. All wetted components have a surface finish better than 16 micro inch Ra. All elastomers are FDA compliant and USP Class VI traceable. The insulator material uses FDA compliant material. The sensor includes a highly accurate RTD. Documentation is standard with each Model 403 sensor that includes lot traceability to facilitate the validation process.

The Solu Comp II Model 1056 outputs raw conductivity and temperature. The Model 1056 can also accept two sensor inputs to make a percent rejection or percent passage measurement. The 1056 includes a USP alarm option that will generate a discreet signal if the water conductivity exceeds the USP value at the measured temperature. The Solu Comp Model Xmt with FOUNDATION FIELDBUS is a digital solution. The Model Xmt can send raw conductivity values and temperature values to a well-designed DCS such as Delta V, which can have the USP Conductivity vs. Temperature tables residing in the system.

INSTRUMENTATION

Model 403 Endurance Conductivity Sensor



- Highly accurate conductivity sensor
- Better than 16 micro inch Ra surface finish
- Highly accurate internal RTD
- Documented Lot traceability on wetted components

Model 1056 Conductivity Analyzer



- Single or dual input
- NEMA 4X (IP65) weatherproof, corrosion-resistant enclosure
- Two Isolated current outputs
- Easy to use menu structure
- USP alarm available

Solu Comp Model Xmt Conductivity Analyzer



- FOUNDATION Fieldbus and HART compatible
- Continuous diagnostic monitoring of sensor performance and for warning or failure
- Easy to use menu structure
- Easy to read display

Temp DegC	Cond uS/cm	Temp DegC	Cond uS/cm	Temp DegC	Cond uS/cm
0	0.6	35	1.5	70	2.5
5	0.8	40	1.7	75	2.7
10	0.9	45	1.8	80	2.7
15	1.0	50	1.9	85	2.7
20	1.1	55	2.1	90	2.7
25	1.3	60	2.2	95	2.9
30	1.4	65	2.4	100	3.1

TABLE 1: RAW CONDUCTIVITY VS. TEMPERATURE USP 28 SECTION <645>

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