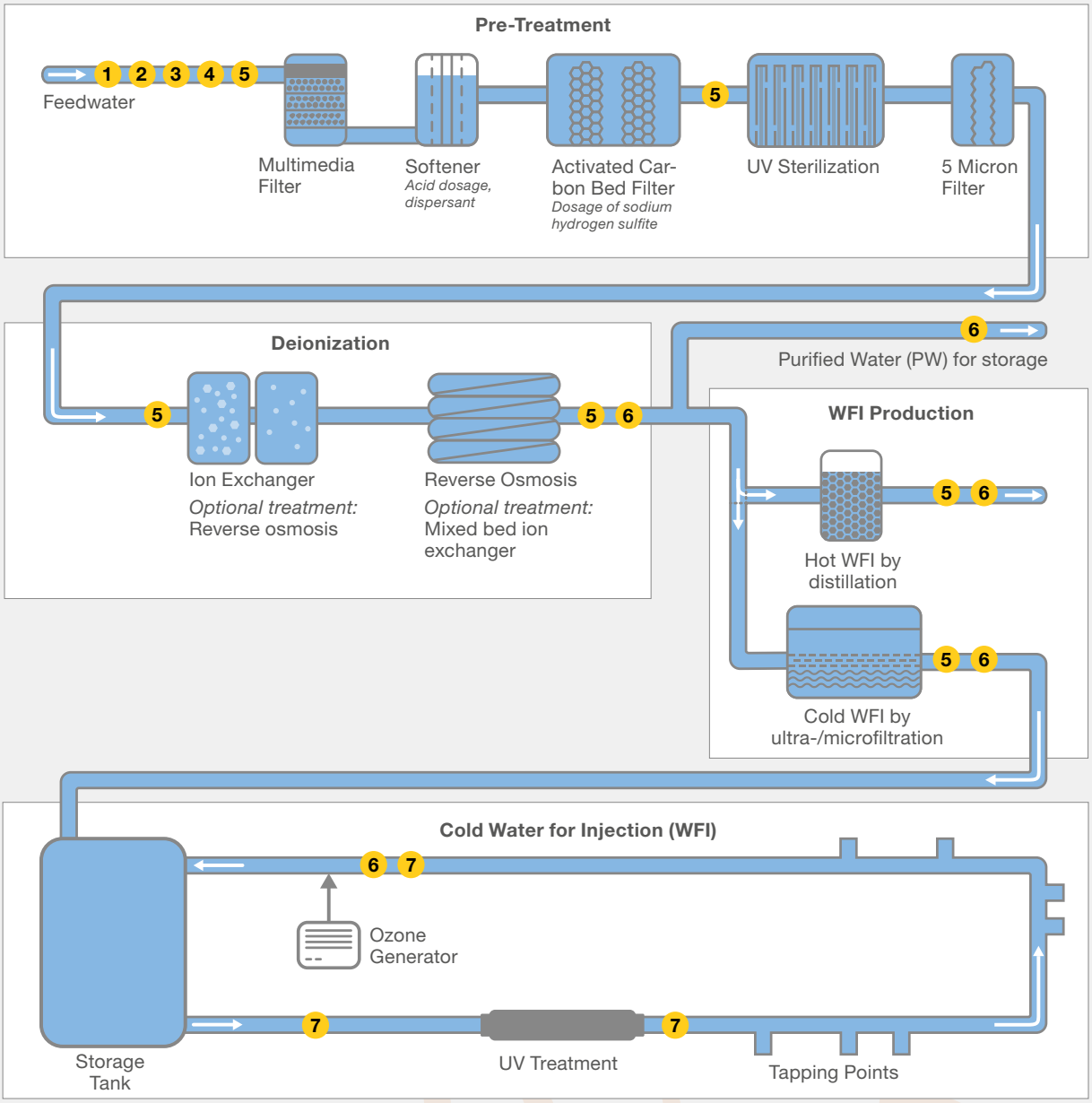
swan
ANALYTICAL INSTRUMENTS

Reliable Online Monitoring of Pharmaceutical Water

Possible Locations for Online Monitoring



Monitoring Points and Key Parameters

1. Chlorine
2. SAC254
3. pH
4. Turbidity
5. Conductivity
6. TOC = Total Organic Carbon
7. Ozone

Introduction

Water is widely used as a process medium, ingredient, and solvent in the processing, formulation, and manufacture of pharmaceutical products, active pharmaceutical ingredients (APIs) and intermediates, compendial articles, and analytical reagents.

Water for Injection (WFI) is a further purification of pharmaceutical purified water (PW) via distillation or ultra-/microfiltration. This last purification step removes bacterial endotoxins from the water. WFI is primarily used in products or processes that come into direct contact with the bloodstream. It is therefore essential that the endotoxin levels are controlled and monitored as they can elicit a pyrogenic response when introduced to the bloodstream.

The legal requirement to comply with pharmaceutical water specifications is defined in the pharmacopoeial monographs. These water specifications can be found in the following pharmacopoeias: USP, Ph Eur and JP.

Parameters	Purified Water (PW)	Water for Injection (WFI)
Conductivity	Eur.Ph.: 5.1 µS/cm @ 25 °C USP: 1.3 µS/cm @ 25 °C	1.3 µS/cm @ 25 °C
Total Organic Carbon (TOC)	≤ 500 ppb	≤ 500 ppb
Total Viable Aerobic Count (using R2A @ 30-35°C for 5 days)	≤ 100 cfu / 100 mL	≤ 100 cfu/10 mL

Reliable TOC Measurement – Total Peace of Mind

The analysis of Total Organic Carbon (TOC) is a non-specific test that reports the weight of carbon in parts per billion (ppb) derived from organic material in the water. TOC is a good indicator of biofilm build-up or system leaks.

Conductivity Monitoring – Simple yet Effective

Performance control of ion exchange units is accomplished by monitoring the conductivity. Comparing the inlet and outlet conductivity identifies when breakthrough occurs – when resins no longer have the capacity to exchange ions – and maintenance is necessary.

Ozone – Convenient Sanitization Control

Dissolved ozone is an effective sanitizer for pharmaceutical water systems. In order to ensure that the levels of ozone meet requirements during the sanitization cycle as well as during normal operation, ozone instrumentation plays a critical role for proper control.

Swan AMI Monitor Concept

Swan instruments are delivered as fully functional, ready-to-use instruments. This ensures easy system integration as well as user-friendly operation and maintainability.

Highest standards in development and production assure the instrument quality expected by our customers.

SWISS MADE

Full System Integration

- Validation packages for straightforward instrument qualification available
- Various communication possibilities with Profibus, Modbus, HART-Protocol, USB-interface and analog output
- Simple process engineering with regulation functions (P, PI, PID or PD), relay or analog output

Easy Maintenance

- Uniform menu navigation for easy operation and maintenance – one platform for all instruments
- Clearly arranged setup of instruments, good accessability of all components for efficient maintenance
- Benefit from service contracts offered by your local Swan representative and enjoy peace-of-mind

Highest Quality Assurance

- Every analyzer is wet bench tested and factory calibrated prior to delivery
- Automatic instrument diagnostics such as reagent level and sensor functions for validated results
- Integrated flow control for validity check

PW/WFI Production

Total Organic Carbon

AMI-II LineTOC

Online monitoring for Total Organic Carbon according to USP <643> and EP 2.2.44

- Reagent-free operation for fast trend identification without costly lab analysis
- Automatic performance verification (SST)
- Integrated grab sample function
- The compact version is ideal for common mounting spaces and has a removable stainless steel cover

Total Organic Carbon (TOC)
0-1000 ppb

Ozone

AMI Codes-II O_3

Photometric ozone measurement per DIN 38408-3

- Reliable measuring results without sensitivity loss even after longer absences of ozone
- Automatic zero point calibration before each measurement guarantees high reproducibility at low detection limit (1 ppb)
- Simple system function verification with optical filter set

Ozone
0-500 ppb

Conductivity

Pharmacon

AMI/AMU transmitters and sensors for monitoring of conductivity

- Uncompensated conductivity with limit alarms according to USP <645> and EP
- Temperature compensation available as non-linear function or by coefficient
- Flexible installation options for sensors by clamp connection or ¾" NPT thread and for transmitters with standardized design

Conductivity
0.055-1000 µS/cm

AMI Inspector

Portable verification of your installed online conductivity meters

- High accuracy online measurement with 3.1 Certificate
- USB data-logger interface and rechargeable battery for self-sufficient operation up to 24 hours
- Transmitter test with high accuracy resistors and manufacturer recertification available

Conductivity
0.055-1000 µS/cm

Pre-Treatment

Chlorine

AMI Codes-II

Photometric measurement for disinfectant concentrations according to AWWA 4500-Cl G/EN ISO 7393-2

- Insensitive to cross-measurements, chemicals and ion interferences
- Automatic zero-value calibration prior to each measurement for high accuracy and reproducibility
- Reduced maintenance with optional cleaning module and high tolerance against fouling

Free Chlorine
0-5 ppm
Chlorine Dioxide, Bromine
0-6 ppm
Ozone
0-1 ppm

SAC254 and Organics, UV Transmission

AMI SAC254

Measurement of UV absorption at 254 nm (SAC254) for organic carbon trending

- Insensitive to fouling of the optical components due to dynamic measurement at multiple path lengths
- Integrated grab sample function
- Correlation to DOC, TOC and other paramaters possible
- Integrated turbidity correction at 550 nm per DIN 38404-3

SAC254
0-300 m^{-1}
UV Transmission
0-100%
DOC, TOC
Concentration ppm

pH/Redox Potential

AMI pH-Redox
AMI pH:mV/pH:mV

Potentiometric measurement of pH value and/or redox potential (single or dual channel)

- Easy calibration without sensor disassembling
- Minimized maintenance with integrated sensor cleaning
- Integrated temperature measurement and pH compensation

pH Range
pH 1-13
Redox Potential (ORP)
-400 – +1200 mV

Turbidity

AMI Turbiwell

Contact-free turbidity measurement; approved alternative method to US EPA 180.1/ISO 7027

- Heated optics prevent measurement errors and condensation
- Applicable for flocculation control (coagulant dosing)
- Automatic measurement chamber flushing; trouble-free operation without manual intervention
- Fast and easy verification with primary and secondary standard
- Optional deltaT flow meter; optional sample degasser to avoid the formation of interfering bubbles in the sample

Turbidity (ISO)
0-200 FNU/NTU
Turbidity (EPA)
0-100 FNU/NTU

Conductivity (Specific)

AMI Solicon4

Measuring of specific conductivity and TDS to be used in all water treatment steps

- Insensitive to fouling due to 4-electrodes principle
- Measurement of salinity as NaCl possible
- Easy calibration without sensor removal
- Optional deltaT sensor for flow detection

Specific Conductivity
0.1 µS/cm-100 mS/cm
Salinity (as NaCl)
0-4.6%
TDS (Coefficient)
0.0 mg/l-20 g/l

Option

Cleaning Module-II

Reliable, accurate measurements ensured by counteracting biogrowth inside the flow cell and photometer

- Individual programmable cleaning interval
- Automatic reagent level monitoring
- Optional module to use conjointly with these monitoring systems:
  - AMI Codes-II
  - AMI SAC254

Pharma Compliance

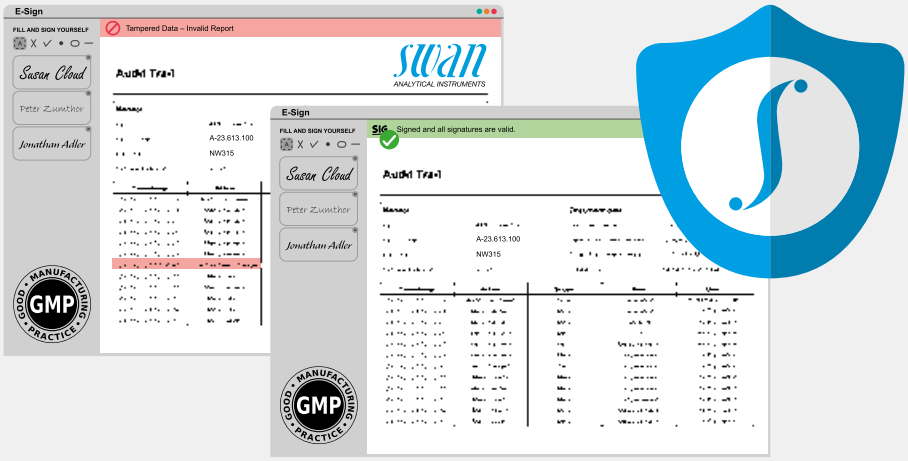
FDA-regulated companies will naturally benefit from more speed and better efficiency, which can be achieved with the right quality management system (QMS).

21 CFR Part 11 simplifies records management and signature processes by permitting the use of digital technology for these quality tasks.

Swan Guard – 21 CFR Part 11 Compliance Software

Swan supports the end-user with thorough implementation of these three features:

- Multi-level user management on the instrument incl. electronic signatures
- Tamperproof audit trail of all manipulations executed on the instrument
- Consistent and complete data incl. calibration history, meta data etc.



Swan supports you in all aspects of pharma compliance

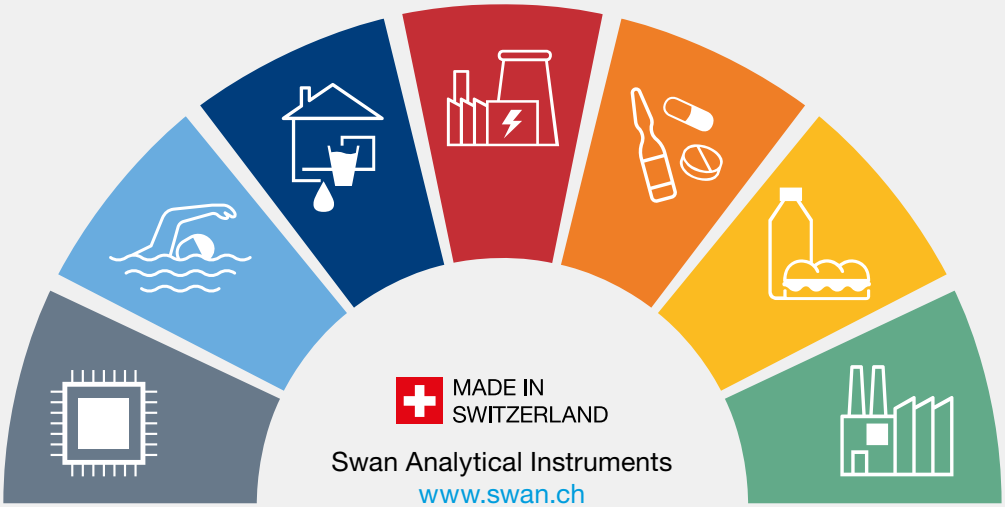
- GMP, GAMP®, ASTM, ISO and ISPE
- FDA 21 CFR Part 11 and Data Integrity (ALCOA Plus)
- US pharmacopoeia such as USP <1231>, USP <645> and USP <643>
- European Medicines Agency (EMA) Annex 1 and Annex 11
- Chinese (ChP), Japanese (JP) and European (Ph. Eur.) pharmacopeia

GOOD MANUFACTURING PRACTICE GMP

swan
ANALYTICAL INSTRUMENTS

- Swan Headquarters
- Swan Subsidiaries
- Distributors

We make water safe.



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