

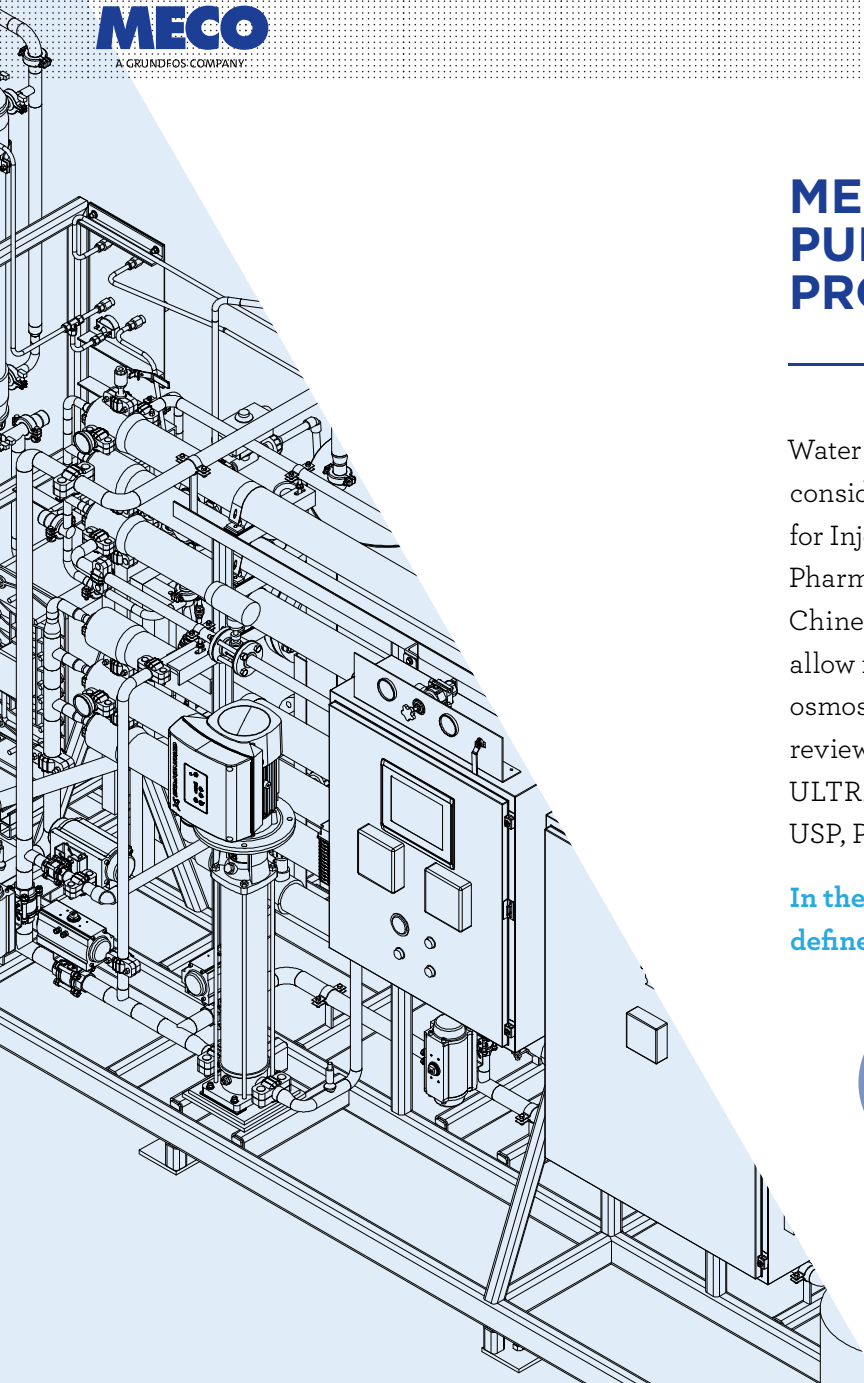
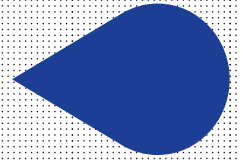
MASTERpak[™] ULTRA
WATER FOR INJECTION

MEMBRANE-BASED WFI SYSTEM





EFFICIENT AND
RELIABLE
MEMBRANE-BASED
WFI SYSTEMS
BACKED BY NEARLY
A CENTURY OF
WATER INDUSTRY
EXPERTISE



MEMBRANE-BASED WATER PURIFICATION SYSTEM FOR WFI PRODUCTION

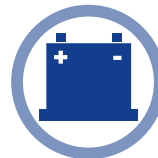
Water is a substantial ingredient in the drug manufacturing process. It is considered a critical utility and is produced in several bulk classifications. Water for Injection (WFI) is one of these classifications described in detail within various Pharmacopeia, including the United States (US), European (Ph. Er.), Japanese and Chinese Pharmacopeias. The USP, Ph. Eur. and JP revised their monographs to allow for WFI production via membrane, at ambient temperatures, such as reverse osmosis and other appropriate technologies. As an industry leader, MECO carefully reviewed these monograph changes and designed the MECO MASTERpak™ ULTRA to produce standard WFI quality water safely and efficiently and meets all USP, Ph. Er., and JP monograph specifications.

In the PH. EUR. and the USP, the major requirements on the purity of WFI are defined as follows:



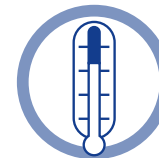
TOC:

< 0.5 ppm



Conductivity:

Ph. Er. <1.1 μ S/cm
(20°C); USP <1.3
 μ S/cm (25°C)



Bacteria:

<10 CFU/100 ml



Endotoxin:

Ph. Er. \leq 0.25
IU/ml;
USP <0.25 EU./ml



MASTERpak™ ULTRA FOR AMBIENT WFI GENERATION

The compact MASTERpak™ULTRA is a complete solution for producing ambient Water for Injection (WFI) using membranes. It integrates MECO's pretreatment, RO, EDI and UF product technologies in an ergonomic design for optimal performance, maintenance and sampling access. This single packaged skid comes with comprehensive services like commissioning, validation and preventive maintenance. This total solution eliminates field integration issues and provides you with exceptional value.



FULLY INTEGRATED HEAT SANITIZATION

A stainless steel break tank is provided with an integral immersion heater for both tempering and achieving sanitization temperatures via PID loop controls. Separate sanitization circuits are integrated into the MASTERpak™ULTRA system. The carbon filter can be sanitized individually, on its own schedule, thus minimizing down time and increasing sanitization effectiveness.



FEED LEVEL CONTROL VALVE

The feed level control valve is automated and positioned for ease of access, and maintains the feed level through a PID loop. This compensates for fluctuation in feed water pressure at the inlet of the skid.



CENTRIFUGAL PUMP

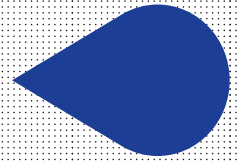
Vertical multistage pump with integral VFD (variable frequency drive) will automatically adjust to maintain a constant feed flow, ensuring a continuous production rate through a PID loop.



ECO RE-CIRCULATION MODE

Recirculation mode during times of no WFI demand to control micro growth and minimize biofilm formation.





The MASTERpak™ULTRA offers scalable standard designs ranging from 0.2 – 16 m³/h (1 – 70 gpm) of WFI. Each unit is factory assembled and fully west-tested prior to shipment. We follow rigorous company standards that exceed current industry guidelines for manufacturing and are ISO 9001 certified. That way, we're able to guarantee that each MASTERpak™ULTRA system will produce the quantity and quality of WFI required.



BUILT-IN CIP CAPABILITY

Built in CIP tank with simple connections throughout for a quick and thorough chemical cleaning and sanitizing process to minimize microbial growth and biofilm formation.



THE ULTIMATE BARRIER

A stand-alone Ultrafilter with a 6,000 Dalton MWCO is employed for superior microbial and endotoxin reduction.



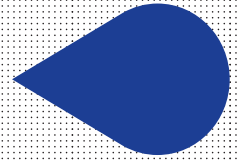
INNOVATIVE CONTROL TECHNOLOGY

GAMP compliant PLC that can integrate with numerous centralized systems. System designed for easy enrollment in MECO's smartANALYTICS™ program for real-time remote monitoring and predictive maintenance.



PROCESS MONITORING

Ensuring consistent conformance with each Pharmacopeia's quality requirements is critical. Process monitoring/sampling of conductivity/TOC/bioburden is available for all MASTERpak™Ultras.



OPERATION AND MAINTENANCE SERVICES

MECO offers different levels of service agreements tailored to meet each customer's specific needs. Our vertically integrated infrastructure and broad array of water and pure steam products enable unique service capabilities and life cycle product support to the industries we serve.

- Services include: Emergency Support, Preventative Maintenance and Full-time O&M
- Mechanical, chemical and electrical field service engineers are factory trained, OSHA 30 and NFPA 70E certified and trained to cGMP Good Documentation Practices
- Full-service capabilities in North America, Europe and Asia
- Remote monitoring and **MECO smartANALYTICS™** system integration available
- Responsive, reliable spare parts department
- Product and process education and training

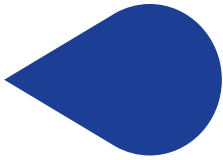
“*The technologies used to produce pure water are not simple. They use sophisticated control systems to produce water to exacting standards from sources that are often variable. Our people are trained experts backed up by experts. We've seen a lot over the years, but we never stop learning.*”

BILL ESSARY, SERVICE MANAGER



WHERE TOMORROW GETS ITS WATER.®





ASIA-PACIFIC

SINGAPORE

390 Havelock Road
#03-06 King's Centre
Singapore 169662 | +65.6836.7500

EUROPE

IRELAND

Roselawn House, University Business Complex
National Technology Park
Co. Limerick, Ireland | +353.61.512.130

UNITED ARAB EMIRATES

ABU DHABI

United Technical Services, P.O. Box 277
Plot No.3E, Sector MN-3
Mussafah Abu Dhabi, U.A.E. | +971.2.617.000

UNITED STATES

HOUSTON, TX

12603 Southwest Freeway, Suite 500
Stafford, TX 77477 | +1.281.276.7600

MANDEVILLE, LA

68375 Compass Way East
Mandeville, LA 70471 | +1.985.249.5500

