

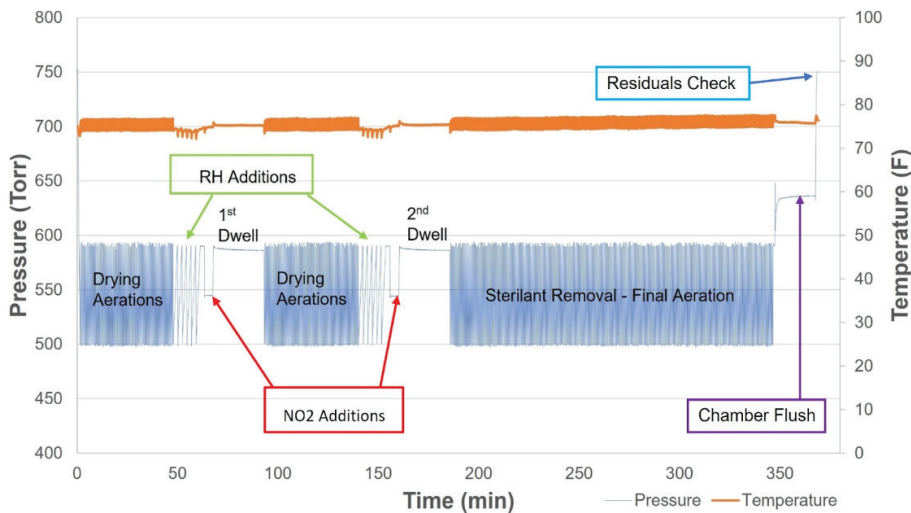


NOXILIZER™

NO₂ STERILIZATION IS THE BEST CHOICE FOR PRE-FILLED SYRINGES, COMBINATION PRODUCTS & INJECTORS



500 Torr Vacuum Cycle Profile



ADVANTAGES OF NO₂ FOR PRE-FILLED SYRINGES:

- Ultra-low temperature process
- Minimum vacuum option prevents stopper movement
- Low/no ingress through stoppers, maintains drug integrity
- Flexible critical process parameters for custom cycles
- Compatible with glass, polymer and lubricants
- Safe and simple to bring in house, improves supply chain

RECENT PUBLICATIONS:

Terumo study finds that NO₂ sterilized WFI-filled syringes have immeasurable NO₂ ingress when compared to EO and VHP, **Chemical-gas Sterilization of External Surface of Polymer-based Prefilled Syringes and Its Effect on Stability of Model Therapeutic Protein**, Fujiwara, et.al., Journal of Pharmaceutical Sciences, September 2021.

Regeneron study notes that Nitrogen Dioxide (NO₂) sterilization ensures drug integrity and lowers the risks of adverse effects with IVT, **Container Closure and Delivery Considerations for Intravitreal Drug Administration**, Parenky, et.al., AAPS PharmSciTech, March 2021.

FOR MORE INFORMATION:

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OR

WWW.NOXILIZER.COM



Materials

- Chamber made of AISI 316L stainless steel
- Piping and valves in stainless steel
- Process compliant materials for all exposed components
- Associated material certifications

Documentation & Compliance

- EU Regulatory electrical Compliance (CE)
- 21CFR Part 11 / EU Annex 11 Compliant
- Documentation: FDS, HDS, SDS, P&ID, GA, NET, CSV, Risk Analysis
- Parametric release capable

Components/Processes

- Single automatic horizontal door
- Dual door gaskets with safety systems
- Jacket for temperature control
- Dry vacuum pump
- External recirculation loop, internal plenum
- Exhaust blower with abator / scrubber
- Gas cabinet and buffer tank for dosing
- UPS system for PLC/Panel PC
- Humidification system
- 0.2µm air inlet filter
- Rockwell PLC, CompactLogixTM 5380
- Rockwell Versaview[®] 6300P HMI (English)
- GE Digital iFix SCADA
- Remote Access Router
- Default Batch Report (English)
- Default User Levels
- Uninterrupted power supply for Control Systems
- Catwalk structure for ease of maintenance
- Emergency Stop function at door and within technical space
- Temperature, pressure and humidity sensors
- High level NO₂ detectors for process control
- Low level NO₂ detectors for safety
- Chamber rails adapted for chosen rack
- Maintenance cycles (leak test, bottle change)
- Configurable sterilization recipe programs
- Closed loop humidity and sterilant control
- Redundant measurement of critical parameters