



sartorius

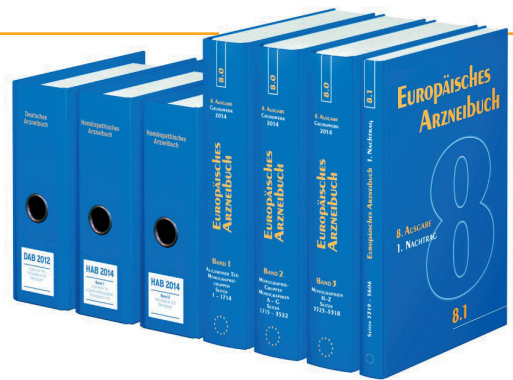
**FOR
INTERNAL USE**

arium® pro VF versus Application Filters

EU Pharmacopoeia – Highly Purified Water

Question: What system configuration achieved the limit values for Highly Purified Water required by EU Pharmacopoeia?

Result: Only two of the configurations tested achieved the required quality.



Type 1 Water

According to the EU Pharmacopoeia standard (focus microbial content <10 cfu/100 mL), Highly Purified Water

Application areas

- Pharmaceutical industry
- Quality control
- Research & development
- Manufacture of medical devices

Increased bacterial counts lead to falsified results, e.g. during:

- Molecular biology applications (proteases | DNases etc.)
- Microbial colony count
- Endotoxin level determination

arium® pro VF

Meets "Highly Purified Water" quality standard:

(Conductivity = 0.055 µS/cm):

- Reliable bacterial retention compliant with EU Pharmacopoeia
- Convincing, reproducible results

Experimental Conditions

arium® pro VF with a sterile final filter versus Millipore MilliQ Advantage A10, with 5 available final filters

- R2A agar (for heterotrophic bacteria) was used to analyze the microbial content. The vacuum filtration method was applied to filter a parallel batch of 100 mL of water through a 13906 filter. The filter was then placed on the agar and incubated for 5–8 days at 32 ± 2 °C. The results of the two agar plates were averaged.



MilliQ Advantage



- Bio-Pak
- VOC-Pak
- EDS-Pak
- LC-Pak

Results

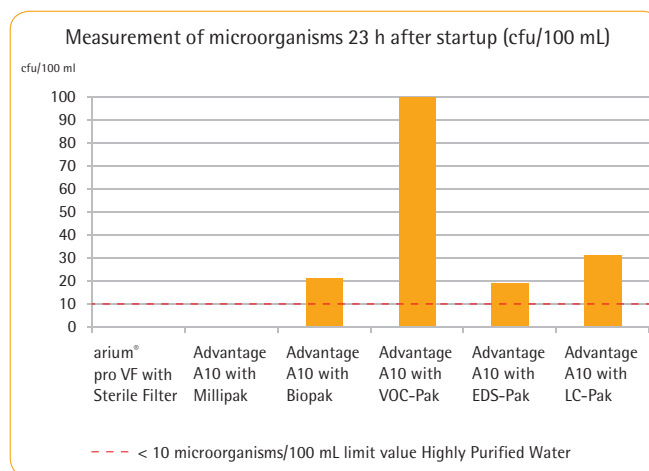
The following graphic provides a summary of the results:

arium® pro VF convinces through:

- Fulfillment of standards (< 10 cfu/mL)
- Highest quality, < 1 cfu/1000 mL
- Consistent quality
- According to HIMA-validated, sterilizing-grade final filter

Competitor Products:

- Achievement of the standard is only possible in conjunction with a sterilizing-grade final filter
- Four out of five of the competitive final filters tested do not meet the requirements of the EU Pharmacopoeia
- Depending on the application, a combination of filters and | or replacement of the filtration unit is mandatory



All filters were put into operation and used in accordance with the manufacturer's instructions.

arium® pro VF – One system fits all

- ▶ Best quality
 - Complies with the European Pharmacopoeia standard for Highly Purified Water
- ▶ The highest process reliability
 - No change of application-related filter components required
- ▶ Practical | flexible
 - Suitable for all life science and analytical applications – simplifies processes

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