

Fachübersetzung der vorläufigen EMA Leitlinie WFI Ph. Eur. aus Membranverfahren



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers on production of water for injections by non-distillation methods – reverse osmosis and biofilms and control strategies

Final

Adopted by GMP/GDP IWG	May 2016
Start of public consultation	5 August 2016
End of consultation (deadline for comments)	4 November 2016

This set of questions and answers is intended to provide preliminary guidance until such time the on-going revision of Annex I of the GMP guide is complete.

Keywords	Water for Injections, reverse osmosis, Biofilms, Control Strategies
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