



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

November 1st , 2016

Submission of comments on:

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

(EMA/INS/GMP/489331/2016)

**Comments from:**

E.I.P.G.

**European Industrial Pharmacists Group**

*Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.*

*When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).*



## 1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
<i>(To be completed by the Agency)</i>	<p>This Q&amp;A guidance is considered very useful as it clarifies many issues which have been under discussion for a long time.</p> <p>In particular, it is appreciated for clarification about:</p> <ul style="list-style-type: none"><li>- The microbiological risks due to biofilm</li><li>- The need of loop and storage tank sterilization with steam and their sanitization</li><li>- The use of ozone</li><li>- The constant monitoring of the microbial contamination of water</li></ul> <p>We hope these clarifications will be promptly acknowledged by users and by inspectors.</p>	<i>(To be completed by the Agency)</i>

## 2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Lines 74-75		Comment: /  Proposed change (if any):  The addition of examples of materials of construct would be useful	
Lines 253-254		Comment:  It would be useful to give some recommendations about the frequency of the “detailed inspection checks” or to better define the criteria to be adopted for these checks in the maintenance plan.  Proposed change (if any): /	
Line 262		Comment: /  Proposed change (if any):  “They are ubiquitous” as unnecessary.	

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Line 334		<p>Comment:</p> <p>It seems more appropriate to refer to the presence of a quality risk management system.</p> <p>Proposed change (if any):/</p>	
Line 347 or line 367		<p>Comment:</p> <p>It would be useful to give a recommendation about the temperature of hot water.</p> <p>Proposed change (if any):/</p>	
Lines 390- 391		<p>Comment:</p> <p>The use of rapid microbiological test methods would not exclude other tests which can be used in real time.</p> <p>Proposed change (if any):/</p>	