EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15th May 2019

Submission of comments on <Guideline on the quality of water for pharmaceutical use> (EMA/CHMP/CVMP/QWP/496873/2018)

Comments from:

Name of organisation or individual
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).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	None	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
92		Comment: No guidance on which test should be conducted at the manufacturing Site to confirm potable water quality Proposed change (if any): Specify that the amount of testing and the limits to confirm potable water quality can be determined by a risk based approach (i.e. Total Microbial Count and exclusion of organisms objectionable for the specific manufacturing process) if the source water is certified as suitable for human consumption	
109-110		Comment: There is no indication about endotoxin level requirement for Purified Water intended to feed pure steam generators (different from Draft Annex 1 – line 715-716) Proposed change (if any): Harmonize text with Annex 1 requiring low level endotoxin PW for feeding pure steam generators	
162 - Table 3 "Fermentation media and cell culture media"		Comment: Purified water is accepted, without any additional specification Proposed change (if any): It would be better to specify that, in this case, purified water is to be sterilised before use	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
162 - Table 3 "Final isolation and purification"		Comment: Potable water is accepted or (*) purified water is required only based on greater chemical purity requirements, without considering possible additional microbiological requirements (in case of an AS with a stricter bioburden level). Furthermore, it should be remembered that the AS manufacturer may not know the final destination of the AS Proposed change (if any): It would be better to expand the note (*), including reference to any additional and/or tighter requirements (chemical and microbiological) as determined by the concerned AS	

Please add more rows if needed.