



01 October-2010

World Health Organization  
1211 Geneva 27  
Switzerland

**SUBMISSION OF COMMENTS ON QAS/09.297 Rev.2:WHO Good Practices for Pharmaceutical Microbiology Laboratories.**

ISPE is pleased to provide comments on the above document, compiled by the Good Control Laboratory Practices (GCLP) Community of Practice within ISPE.

Our comments pertain specifically to the areas of environment, equipment, sampling and testing procedures.

Our comments have been submitted, as requested, using the supplied WHO template.

We would much appreciate if the comments detailed in the document are addressed.

Yours sincerely,

Robert P. Best  
President/CEO, ISPE

**Comments on WHO Working Document QAS/09.297/Rev.2**  
**Title of the document : WHO Good Practices for Pharmaceutical Microbiology Laboratories**



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Date : 07-September-2010

*Kindly complete the table without modifying the format of the document - thank you.*

Template for comments

<b>General comment(s) if any :</b>	<b>Originator of the comments</b>
None	

# section	# Paragraph If more than one	Comment / Rationale	Proposed change / suggested text	Classification L= low M= medium H= high	Originator of the comments (for WHO use)
2	2.1.6	Permitting activities without segregation and following risk assessment approach may lead to lot of personal assessments and should be avoided. Suggest rewrite the paragraph as shown	Sterility testing should always be performed in a dedicated area. Other laboratory activities, such as sample preparation, media and equipment preparation and enumeration of microorganisms, should be confined to the area earmarked for the activity or segregated by space or time, so as to minimize risks of cross-contamination and false positives	M	
2	2.1.7	Table of different zones	Suggest the table be attached as an appendix	L	
4	4.3.5 Last	This paragraph gives an option of using one autoclave for sterilization and decontamination with	Delete this paragraph.	H	

# section	# Pararaph If more than one	Comment / Rationale	Proposed change / suggested text	Classification L= low M= medium H= high	Originator of the comments (for WHO use)
	Para	documented cleaning programme. This is not acceptable, decontamination autoclave should be different.			
7	7.2	Last sentence of this sub-section states “Testing of the samples should be performed as soon as possible after sampling.” This is ambiguous for testing of water samples.	Include a definitive statement for storage period for water samples, generally within 4 hours of sampling	M	
11	11.1.2	Statement on standards has a typographical error.	Modify the statement as – microbial limit testing / total bio-burden 1000 cfu per g for bacteria and 100 cfu per g for yeast and moulds.	H	
11	11.1.2	Standard for environmental monitoring is vague. It does not say exposure of plates for how long. There is also no mention about active air sampling.	Standard should state duration of exposure e.g.: 2 hours, 4 hours etc. Also include active air sampling requirements.	H	

End of document