



17 August 2010

World Health Organization
1211 Geneva 27
Switzerland

SUBMISSION OF COMMENTS ON QAS/08.251/Rev.1: WHO Pharmaceutical Development for Multisource (Generic) Pharmaceutical Products

ISPE is pleased to provide comments on the above document.

Our comments relate to the general nature of the document pertain specifically to the references related to bioequivalence to the comparator product, as well as inclusion of acronyms in the Glossary section of the document.

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/08/251/Rev.1

Title of the document: Pharmaceutical Development for Multisource (Generic) Pharmaceutical Products



Comments submitted by : International Society for Pharmaceutical Engineering - ISPE

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

Template for comments

General comment(s) if any :	Originator of the comments

# 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)
1.	2	At the start of paragraph 2, there is a statement that the guideline focuses on the development of multi-source pharmaceutical products which are bioequivalent to the relevant comparator. The rest of the document seems to deal with the wider issue of multi-sourced products, as defined in the Glossary, rather than the narrower restriction to those which are bioequivalent. This is an inconsistency that should be addressed.		M	ISPE
6.5.1		Change the wording of this section to reflect the wider scope that this document should have, including instances where bioequivalence is not needed.	"Bioequivalence when needed and comparative dissolution studies should be conducted....."	M	ISPE
	Glossary	The Glossary is good; however, a list of the	Add a list of abbreviations.	L	ISPE

# 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)
		abbreviations used throughout the document would be useful and would facilitate the document being read by those less familiar with the activities it describes.			
		<i>Please add rows as necessary (with "copy and paste" empty rows)</i>			