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Committee for Medicinal Products for Human Use (CHMP)

Oseltamivir Product-Specific Bioequivalence Guidance

Draft

Draft Agreed by Pharmacokinetics Working Party	**October 2013**
Adoption by CHMP for release for consultation	24 October 2013
Start of public consultation	15 November 2013
End of consultation (deadline for comments)	15 February 2014

Comments should be provided using this template. The completed comments form should be sent to PKWPsecretariat@ema.europa.eu.

Keywords	***Bioequivalence, generics, oseltamivir***

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Oseltamivir Product-Specific Bioequivalence Guidance

Disclaimer:

This guidance should not be understood as being legally enforceable and is without prejudice to the need to ensure that the data submitted in support of a marketing authorisation application complies with the appropriate scientific, regulatory and legal requirements.

Requirements for bioequivalence demonstration (PKWP)*

BCS Classification**	**BCS Class:** ☐ **I** ☐ **III** ☒ **Neither of the two** **Background:** The available data on solubility does not allow the BCS classification of oseltamivir. If the Applicant generates the solubility data and classifies the drug according to the BCS criteria as highly soluble, a BCS biowaiver could be applicable.
BE Study design	**single dose** **cross-over**
	healthy volunteers

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	☒ **fasting** ☐ **fed** ☐ **both** ☐ **either fasting or fed**
	Strength: 75 mg capsules because it is the highest strength **Background**: The highest strength is recommended for bioanalytical reasons. 75 mg is also the typical single dose for adults.
	Number of studies: One single dose study
	The solution may be waived if the same amount of sorbitol is used as in the originator.
Analyte	☒ **parent** ☐ **metabolite** ☐ **both**
	☒ **plasma** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** AUC_{0-t}, Cmax
	90% confidence interval: 80.00– 125.00

16 * As drug variability has not been reviewed, this guidance is not applicable to highly variables drugs.

17 ** The BCS classification should be confirmed by the Applicant at time of submission based on available data (solubility experiments, literature, etc.). If
18 a drug substance has been classified as BCS class II or IV, no further solubility investigations are needed.