EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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3 Committee for Medicinal Products for Human Use (CHMP)

4 Emtricitabine/Tenofovir Disoproxil Product-Specific 5 Bioequivalence Guidance

6 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

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

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Keywords	***Bioequivalence, generics, emtricitabine, tenofovir disoproxil***

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Emtricitabine/Tenofovir Disoproxil 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:** Emtricitabine is considered a high solubility and permeability compound, tenofovir disoproxil is considered a high solubility and low permeability compound.
BE Study design	**single dose** **cross-over**
	healthy volunteers

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	☐ **fasting** ☒ **fed** ☐ **both** ☐ **either fasting or fed**
	Strength: Emtricitabine 200 mg and tenofovir disoproxil 245 mg
	Number of studies: one single dose study
Analyte	☒ **parent** ☒ **metabolite** ☐ **both** **Background:** For emtricitabine the parent, for tenofovir disoproxil the metabolite (as tenofovir).
	☒ **plasma** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** AUC_{0-t} and Cmax
	90% confidence interval: 80.00– 125.00

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

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