EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Erlotinib 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, erlotinib***

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Erlotinib 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:** Erlotinib may be considered a low solubility compound.
BE Study design	**single dose** **cross-over**
	healthy volunteers

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	☒ **fasting** ☐ **fed** ☐ **both** ☐ **either fasting or fed**
	Strength: 150 mg because it is the highest strength **Background:** Highest strength for substances with low solubility and linear pharmacokinetics
	Number of studies: one single dose study
Analyte	☒ **parent** ☐ **metabolite** ☐ **both**
	☒ **plasma** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** AUC_{0-72h} 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.