1 14 December 2017
2 EMA/CHMP/800785/2017
3 Committee for Medicinal Products for Human Use (CHMP)

4 Posaconazole gastro-resistant tablet 100 mg product-5 specific bioequivalence guidance

6 Draft

Draft Agreed by Pharmacokinetics Working Party (PKWP)	November 2017
Adopted by CHMP for release for consultation	14 December 2017
Start of public consultation	31 January 2018
End of consultation (deadline for comments)	30 April 2018

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

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Keywords	***Bioequivalence, generics, posaconazole***

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Posaconazole gastro-resistant tablet 100 mg 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)*

Bioequivalence study design**	**single dose fasting: 100 mg** **single dose fed: 100 mg** **healthy volunteers**
	cross-over
Analyte	☒ **parent** ☐ **metabolite** ☐ **both**
	☒ **plasma/serum** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** $AUC_{(0-t)}$, AUC_{inf} and C_{max} **Background/justification:** delayed release formulation

	90 % confidence interval: 80.00 – 125.00%

* As intra-subject variability of the reference product has not been reviewed to elaborate this product-specific bioequivalence guideline, it is not possible to recommend at this stage the use of a replicate design to demonstrate high intra-subject variability and widen the acceptance range of C_{max}, $C_{\tau,ss}$ and partial $_{AUC}$. If high intra-individual variability (CVi_{intra} > 30 %) is expected, the applicants might follow respective guideline recommendations.

** For prolonged release formulations: If a single-dose study with the highest strength has shown that there is low risk of accumulation (i.e. AUC_{τ} > 90% of AUC_{inf}), the multiple-dose study may be waived. If low degree of accumulation is expected, the applicants might follow respective guideline recommendations.