EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Fampridine prolonged-release tablet 10 mg product-specific bioequivalence guidance

Draft agreed by Pharmacokinetics Working Party (PKWP) / Methodology Working Party (MWP)	February 2023
Adopted by CHMP for release for consultation	30 March 2023
Start of public consultation	June 2023
End of consultation (deadline for comments)	30 September 2023
Agreed by Methodology Working Party (MWP)	
Adopted by CHMP	
Date for coming into effect	

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

Keywords	***Bioequivalence, generics, fampridine***

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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:** 10 mg, healthy volunteers. **Single dose fed:** 10 mg, healthy volunteers. **Multiple dose fasting:** 10 mg, healthy volunteers. **Background:** Single dose (fasting and fed) and multiple dose studies are required for prolonged release formulations with accumulation.
	cross-over
Analyte	☒ **parent** ☐ **metabolite** ☐ **both**
	☒ **plasma/serum** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** Single dose: AUC_{0-t}, AUC_{0-inf}, and C_{max} Multiple dose: $AUC_{0-\tau,ss}$, $C_{max,ss}$, and $C_{\tau,ss}$

	90% confidence interval: 80.00–125.00% **Background:** Fampridine is not considered a narrow therapeutic index drug for the purpose of establishing bioequivalence of generics.

* 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.