EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Ibrutinib hard capsules 140 mg and film-coated tablets 140, 280, 420 & 560 mg product-specific bioequivalence guidance

Draft Agreed by Pharmacokinetics Working Party (PKWP)	28 October 2020
Adopted by CHMP for release for consultation	11 November 2021
Start of public consultation	16 December 2021
End of consultation (deadline for comments)	31 March 2022
Agreed by Pharmacokinetics Working Party	08 June 2022
Adopted by CHMP	23 June 2022
Date for coming into effect	01 January 2023

Keywords	***Bioequivalence, generics, ibrutinib***

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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)*

BCS Classification	**BCS Class:** ☐ **I** ☐ **III** ☒ **Neither of the two** **Background:** Ibrutinib may be considered a low solubility compound with complete absorption.
Bioequivalence study design *in case a BCS biowaiver is not feasible or applied*	**single dose** **cross-over**
	healthy volunteers
	☒ **fasting** ☐ **fed** ☐ **both** ☐ **either fasting or fed**
	Strength: 140 mg for the capsules and 560 mg for the tablets **Background:** Highest strength to be used for a drug with linear pharmacokinetics and low solubility.
	Number of studies: One single dose study for each dosage form.
Analyte	☒ **parent** ☐ **metabolite** ☐ **both**

	☒ **plasma/serum** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** AUC_{0-t} and C_{max}
	90% confidence interval: 80.00–125.00%

* Since high intra-subject variability (CV_{intra} > 30%) is expected, the applicants might follow respective guideline recommendations.