14 April 2025
EMA/123564/2025 Rev. 1*
Committee for Medicinal Products for Human Use (CHMP)

# Posaconazole oral suspension 40 mg/ml product-specific bioequivalence guidance*

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| **Draft agreed by Pharmacokinetics Working Party (PKWP)** | 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 |
| **Agreed by Pharmacokinetics Working Party** | March 2015 |
| **Adoption by CHMP** | 26 March 2015 |
| **Date for coming into effect** | 1 October 2015 |
| **Draft revision agreed by Methodology Working Party (MWP)** | 3 April 2025 |
| **Adopted by CHMP** | 14 April 2025 |
| **Date of coming into effect** | 1 November 2025 |

* This revision addresses textual changes in study conditions and dosing recommendations in line with the ICH M13A guideline

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

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# Posaconazole oral suspension 40 mg/ml 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 (MWP)*

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| **BCS Classification**** | **BCS Class:** ☐ **I** ☐ **III** ☒ **neither of the two**<br>**Background:** Posaconazole may be considered a low solubility compound with complete absorption. |
| **Bioequivalence study design**<br>*in case a BCS biowaiver is not feasible or applied* | **single dose**<br>**cross-over** |
| | **healthy volunteers** |
| | ☐ **fasting** ☒ **fed** ☐ **both** ☐ **either fasting or fed**<br>**Background:** Posaconazole oral suspension should be taken with a meal. |
| | **Strength:** 40 mg/ml. Any recommended clinical dose can be used.<br>**Background:** The oral suspension is the only registered oral immediate release formulation. It has its own SmPC and is not exchangeable with the enteric coated tablet formulations. The dose to be employed in the |

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| | BE study for an oral suspension should follow the recommended dosing, or one of the doses, as per the SmPC. |
| | **Number of studies:** One single dose study. |
| **Analyte** | ☒ **parent** ☐ **metabolite** ☐ **both** |
| | ☒ **plasma/serum** ☐ **blood** ☐ **urine** |
| | **Enantioselective analytical method:** ☐ **yes** ☒ **no** |
| **Bioequivalence assessment** | **Main pharmacokinetic variables:** $AUC_{0\text{-}72h}$ and $C_{max}$ |
| | **90% confidence interval:** 80.00– 125.00% |

* As high intra-individual variability (CVintra > 30 %) is expected, the applicants might follow respective guideline recommendations.

** This tentative BCS classification of the drug substance serves to define whether *in vivo* studies seem to be mandatory (BCS class II and IV) or, on the contrary, (BCS Class I and III) the Applicant may choose between two options: *in vivo* approach or *in vitro* approach based on a BCS biowaiver. In this latter case, the BCS classification of the drug substance should be confirmed by the Applicant at the time of submission based on available data (solubility experiments, literature, etc.). However, a BCS-based biowaiver might not be feasible due to product specific characteristics despite the drug substance being BCS class I or III (e.g. *in vitro* dissolution being less than 85 % within 15 min (BCS class III) or 30 min (BCS class I) either for test or reference, or unacceptable differences in the excipient composition).