15 October 2026
EMA/208474/2026
European Medicines Agency

Considerations regarding the implementation of ICH M13B on bioequivalence for immediate-release solid oral dosage forms

Adopted by CHMP	15 October 2026

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Introduction

ICH M13B Guideline on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver Step 5 (EMA/CHMP/ICH/85092/2025) is intended to provide recommendations on obtaining waivers of bioequivalence (BE) studies for one or more additional strengths of a drug product in an application where in vivo BE has been demonstrated for at least one of the strengths. The guideline is applicable during both development and post-approval phases of orally administered immediate release (IR) solid dosage forms designed to deliver drugs to the systemic circulation, such as tablets, capsules, and granules/powders for oral suspension.

The ICH M13B Guideline is the second guideline in a foreseen ICH series (ICH M13A, M13B and M13C) describing the scientific and technical aspects of study design and data analysis to support BE assessment for orally administered IR solid oral dosage forms. For more information on ICH harmonisation of BE, please refer to the dedicated ICH M13 page.

The purpose of this implementation document is to address specific considerations to enable the practical application of ICH Guideline M13B in the European Union and the transition from the current EMA Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1). This document is intended to provide guidance for Marketing Authorisation Applicants and Marketing Authorisation Holders, Contract Research Organisations, and Regulators.

Background

Six months after adoption by CHMP, ICH M13B is effective as of 17 March 2027, formally superseding applicable parts of the previously enforced EMA Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) which had been in effect since 1 August 2010. From the date of its coming into effect, stakeholders are required to follow recommendations from the ICH M13B Guideline.

Specifically, ICH M13B supersedes Section 4.1.6 'Strength to be investigated' and Section 4.2.2 'In vitro dissolution tests in support of biowaiver of strengths' of the existing EMA Guideline.

After 17 March 2027, the EMA Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) pertaining to the specific topics not addressed in M13A and M13B will continue to apply until such time as they are replaced by new ICH guidance.

It is therefore highlighted that the requirements of both ICH M13A and M13B and the existing EMA Guideline read in conjunction may be applicable to e.g., • BE studies with highly variable drugs (replicate design) • drugs with narrow therapeutic index, and • complex BE study design and data analysis e.g., • adaptive design. Therefore, any deviation from any guideline will need to be appropriately scientifically justified.

Implementation Strategy

EMA has reviewed its existing Product-specific bioequivalence guidance | European Medicines Agency (EMA), (which were previously to be read in conjunction with the general requirements of EMA Guideline on the investigation of bioequivalence) to determine if they are compatible with the requirements of ICH M13A and these have been revised as needed. EMA will now review its product-specific bioequivalence guidelines to confirm that they meet the requirements of ICH M13B. In the meantime, the product-specific guidelines will need to be also read in conjunction with the requirements of ICH M13B and again, any deviations from the ICH or EMA Guidelines will need to be appropriately scientifically justified.

In addition, the existing Clinical pharmacology and pharmacokinetics: questions and answers | European Medicines Agency (EMA) have been revised in line with ICH M13A but these should now also be read in conjunction with ICH M13B until a further EMA review has been completed.

It is expected that ultimately the EMA Guideline on the investigation of bioequivalence will be replaced by the ICH series and withdrawn. EMA therefore commits to update implementation of the ICH series as the abovementioned harmonisation efforts related to bioequivalence further advance.

In what concerns the implementation of ICH M13B requirements for regulatory submissions:

- If you are still in the planning stage for BE studies on 17 March 2027, you should segue to implementing M13B.
- Bioequivalence studies included in a regulatory submission submitted after 17 March 2027 should be in compliance with the requirements of ICH M13B. Any deviation from the requirements (e.g. studies conducted in compliance with EMA guideline and finalised before ICH M13B became effective) should be discussed in the respective application and will be assessed on a case-by-case basis. The Applicant may consider contacting the relevant competent authority to discuss the particular circumstances of the application.