This guidance, which interprets the Agency’s regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

This is a new draft product-specific guidance for industry on generic meloxicam.

Active Ingredient: Meloxicam

Dosage Form; Route: Solution; intravenous

Strength: 30 mg/vial

Recommended Study: In vitro option

I. In vitro option

The proposed test drug product should be qualitatively (Q1)¹ and quantitatively (Q2)² the same as the Reference Listed Drug (RLD). Bioequivalence may be established based on comparative

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¹ Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference product.
² Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ±5% of those used in the reference product.
in vitro testing of three exhibit batches of both the test product and designated Reference Standard (RS) product include:\(^3\)

- Polymorphic form of meloxicam, pH, osmolality, and zeta potential.

- Drug particle size distribution; The particle size distribution should be compared using population bioequivalence (PBE) (95% upper confidence bound) based on D50 and SPAN [i.e. \((D90-D10)/D50\)]. Please refer to the product-specific Guidance on Budesonide inhalation suspension for additional information regarding PBE. If applicable, information on the instrument, analysis mode, dilution medium, and level of dilution used for particle size measurements should be submitted along with full profiles of the particle size distribution upon serial dilution.

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\(^3\) The manufacturing process for the exhibit batches should be reflective of the manufacturing process to be utilized for commercial batches.