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## Draft Guidance on Cefepime Hydrochloride; Enmetazobactam

December 2025

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<b>Active Ingredient:</b>	Cefepime hydrochloride; Enmetazobactam
<b>Dosage Form:</b>	Powder
<b>Route:</b>	Intravenous
<b>Strength:</b>	EQ 2 gm Base/vial; 0.5 gm/vial
<b>Recommended Study:</b>	Request for waiver of in vivo bioequivalence study requirements

To qualify for a waiver from the requirement for submission of evidence of in vivo bioequivalence on the basis that bioequivalence is self-evident under 21 CFR 320.22(b)(1), a generic cefepime hydrochloride and enmetazobactam powder for intravenous use product should be qualitatively (Q1)<sup>1</sup> and quantitatively (Q2)<sup>2</sup> the same as the reference listed drug (RLD).

An applicant may seek approval of a drug product that differs from the RLD in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.<sup>3</sup>

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<sup>1</sup> Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the RLD.

<sup>2</sup> Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within  $\pm 5\%$  of those used in the RLD.

<sup>3</sup> 21 CFR 314.94(a)(9)(iii).