Contains Nonbinding Recommendations

Draft Guidance on Daptomycin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Daptomycin

Dosage Form; Route: Powder; IV (infusion)

Strength: 350mg/vial

Recommended Study: Request for waiver of in vivo bioequivalence study

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I. Waiver:

To qualify for a waiver from submitting an in vivo bioequivalence (BE) study on the basis that BE is self-evident under 21 CFR 320.22(b), a generic Daptomycin IV infusion powder product must be qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the Reference Listed Drug (RLD).

An applicant may seek approval of a drug product intended for parenteral use 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.[3]

[1] Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference listed drug.
[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 listed drug.
[3] 21 CFR 314.94(a)(9)(iii).