Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Sumatriptan Succinate

November 2022

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Sumatriptan succinate

Dosage Form; Route: Injectable; subcutaneous

Strength: EQ 6mg base/0.5 mL

Recommended Studies: Request for wavier of in vivo bioequivalence study requirements

The Reference Listed Drug (RLD) has two presentations: (1) a single-dose vial, and (2) single-dose, prefilled syringe cartridges that are co-packaged with an autoinjector pen and a carrying case. This guidance provides recommendations for presentation (1), the single-dose vial.

Waiver of in vivo bioequivalence study requirements:

In vivo bioequivalence study may be waived on the basis that bioequivalence is self-evident under 21 CFR 320.22(b), for a generic sumatriptan succinate injectable product is qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the RLD formulation.

An applicant may seek approval of a drug product that differ from the RLD in preservative, buffer or antioxidant if 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 T formulation uses the same inactive ingredient(s) as the R formulation.
[2] Q2 (quantitative sameness) means that concentrations of the inactive ingredient(s) used in the T formulation are within ± 5% of those used in the R formulation.
[3] 21CFR 314.94(a)(9)(iii)

Revision History: Recommended November 2019; Revised November 2022

Unique Agency Identifier: PSG_020080-Vial