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Draft Guidance on Secretin Synthetic Human

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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.

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This is a new draft product-specific guidance for industry on generic secretin synthetic human.

Active Ingredient: Secretin synthetic human

Dosage Form; Route: For solution; intravenous

Recommended Studies: Request for waiver of in vivo bioequivalence study requirement

To qualify for a waiver of the in vivo bioequivalence study requirement on the basis that bioequivalence is self-evident under 21 CFR 320.22(b), a generic secretin synthetic human solution product must be qualitatively (Q1) and quantitatively (Q2) 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.

In addition to ensuring active pharmaceutical ingredient API sameness (i.e., same primary sequence and physicochemical properties) for the drug substance, it is recommended to conduct

the following comparative analyses of the proposed generic secretin and the RLD product on no less than three batches of the proposed drug product tested on or near release and at the end of the proposed shelf life and no less than three batches of the RLD aged tested prior to expiry, after aging under conditions consistent with the label storage conditions.

1. API-related impurity profile comparison
2. Secondary structure
3. Oligomer/aggregation states: oligomer/aggregation propensity and the nature of the aggregates formed for the proposed product should be similar to that of the RLD
4. Biological activities¹

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¹ Applicant may provide justification for not conducting biological assays as part of the comparative analyses if there is evidence that the structure of the API peptide would not interfere with the functional activity.