Contains Nonbinding Recommendations

Draft Guidance on Tetracaine Hydrochloride; Oxymetazoline Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Spray; nasal

Recommended Studies: In vitro studies

FDA recommends the following in vitro studies to establish bioequivalence (BE) of the test (T) and reference (R) nasal sprays containing tetracaine hydrochloride and oxymetazoline hydrochloride.

In Vitro Studies

FDA recommends that applicants conduct the following in vitro BE studies on samples from each of three or more batches of the T product and three or more batches of the R product, with no fewer than 10 units from each batch. A single batch of solution can be split-filled into three equal size sub-lots of product. The sub-lots should be prepared from three different batches of the same critical device components.

1. Single actuation content
2. Droplet size distribution by laser diffraction
3. Drug in small particles/droplets
4. Spray pattern
5. Plume geometry

Additional Comments: Refer to the product-specific guidance for Fluticasone Propionate Nasal Spray Metered[1] for recommendations on design and equivalence criteria for the aforementioned in vitro BE studies, and general recommendations on the conduct of the in vitro BE studies and data submission.[2]

---

[1] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM461051.pdf
[2] Specific recommendations for in vitro BE testing at various life stages are not relevant for this product, given it is a single-use configuration

Additional Information

Formulation:

FDA recommends that the T product be qualitatively (Q1)[3] and quantitatively (Q2)[4] the same as the R product.

Device:

FDA recommends that the T product be similar in shape, size, and external operating principles to ensure substitutability with the R product.

[3] Q_1 (qualitative sameness) means that the T product uses the same inactive ingredient(s) as the R product.

[4] Q_2 (quantitative sameness) means that concentrations of the inactive ingredient(s) used in the T product are within ± 5% of those used in the R product.