Your Generics & Biosimilars Industry

Demonstrating Sameness Between U.S. Reference Standard and Foreign Reference Standard

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Agenda

- Research Request
- Global Regulator Perspectives
- Recommendations
- Benefits of the Research Outcome
- Summary

What is the Research Request?

Conduct research to establish criteria that could be used as a basis to demonstrate sameness between the U.S. Reference product to the Foreign Reference product.

Review of Global Regulators Perspective on Demonstrating Sameness

Both Health Canada and Therapeutic Goods Administration (TGA-Australia) allow the use of Foreign Reference standards for products that meet the general criteria.

- Registered in a country with a comparable regulatory system
- Marketed in the country of origin by the same innovator, company, or corporate entity which markets same product in their country
- Should not be a narrow therapeutic index drug or require careful patient monitoring

Criteria for Demonstrating Sameness by TGA-Australia

Demonstrating sameness by:

- Assessment/comparison of labeling and product information
- C of As for both reference products
- Comparative dissolution profiles in at least 3 media
- Same nominal quantity of drug substance
- Same size, weight and type of coating
- Physicochemical evidence products are quantitatively identical

Criteria for Demonstrating Sameness by Health Canada

Demonstrating sameness for solid oral, immediate-release dosage form:

- Assessment/comparison of labeling
- Identical amount of the identical medicinal ingredient
- C of As for both reference products
- Medicinal ingredient is considered to have high solubility
- Same color, shape, size, weight, type of coating and scoring configuration
- Non-medicinal ingredients qualitatively the same
- Comparative dissolution profiles in 3 media

Criteria for Demonstrating Sameness by Health Canada

Demonstrating sameness in Canada's immediate-release orally inhaled dry powders:

- Assessment/comparison of labeling
- Identical amount the identical of medicinal ingredient
- C of As for both refence products
- Formulation: non-medicinal ingredients are qualitatively and quantitatively the same (±5% of each excipient)
- Physicochemical properties and in-vitro performance essentially the same (±10%)
- Device Attributes: qualitative and quantitative analysis of physical and operating characteristics of the devices

Recommendations

Conduct research to establish criteria that could be used as a basis to demonstrate sameness between the U.S. Reference product to the Foreign Reference product for following dosage forms:

Solid Oral Immediate-release

Solid Oral Modified-release

Complex Drug Products :

- Complex APIs
- Complex formulations
- Complex routes of delivery
- Complex dosage forms

Benefits of the Research Outcome

- Public Safety
- Timely Development & Approval of Generics
- Increased Access to Affordable Medications
- Support Global Development

Summary

In order to improve patient access to high quality affordable generic drugs:

- This research outcome can provide industry with guidance on how to demonstrate sameness between U.S. Reference standard and Foreign Reference standard.
- Revision of regulations could be envisioned based on the outcome of the research to allow for the use of Foreign Reference standards to conduct a bioequivalence studies to support generic drug approval in the U.S.

Thank You

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