Contains Nonbinding Recommendations

Draft Guidance on Soybean Oil

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Injectable; injection

Strength: 10% and 20%

Recommended Studies: In vitro option or in vivo option

In vitro option[1]:

The comparative study should be performed on at least three batches of the Test and the RLD products.

Parameters to measure: Globule size distribution. The sponsors should also perform other physicochemical characterizations, including, but not limited to, zeta potential, pH, osmolality and viscosity profile, on the Test and the RLD products. In addition, the sponsors should compare the size parameter upon serial dilution (if applicable) of the Test and the RLD products, and provide histograms of globule size distribution data of each diluted sample.

Bioequivalence based on (95% upper confidence bound): Population bioequivalence (PBE) based on D_{50} and SPAN (alternatively harmonic intensity weighted average particle diameter and polydispersity index derived from cumulate analysis of the intensity size distribution) for the particle size distribution only (the other parameters do not require PBE analysis). The applicants should provide no less than 10 datasets from 3 batches each of the Test and the RLD products to be used in the PBE analysis.

In vivo option:

Type of study: Fasting
Design: Single-dose, randomized, two-way crossover
Strength: 10% and 20%
Subject: Normal healthy males and females
Additional Comments: (1) The subjects should be encouraged to remain sedentary to minimize the activity. (2) PK parameters should be computed from the individual baseline-adjusted measurements.

[1] The in vitro option can only be used to demonstrate BE when the Test and the RLD products are qualitatively and quantitatively the same (Q1/Q2). Q1 (qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference product. Q2 (quantitative sameness) means that the concentrations of the inactive ingredient(s) used in the test product are within ± 5% of those used in the reference product.

Analytes to measure (in appropriate biological fluid): Triglycerides in serum

Bioequivalence based on (90% CI): Triglycerides in serum

Dissolution test method and sampling times: Not applicable