**Draft Guidance on Triclabendazole**

**Active Ingredient:** Triclabendazole

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. **Type of study:** Fasting  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 250 mg  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** Monitor ECG in study subjects with a history of prolongation of the QTc interval or a history of symptoms compatible with a long QT interval.

2. **Type of study:** Fed  
   **Design:** Single-dose, two-treatment, two-period crossover in vivo  
   **Strength:** 250 mg  
   **Subjects:** Males and non-pregnant, non-lactating females, general population  
   **Additional comments:** See comments above

**Analytes to measure (in appropriate biological fluid):** Triclabendazole and its active metabolite, triclabendazole sulfoxide, in plasma

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

**Bioequivalence based on (90% CI):** Triclabendazole

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units for each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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If the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per Guidance for Industry on Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.