Ana Maria Ghelidiu et al., Drug Des 2018, Volume 7
DOI: 10.4172/2169-0138-C2-025

The relative bioavailability of two pharmaceutical formulations containing triclabendazole in healthy sheep

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A study was carried out to evaluate the pharmacokinetics of triclabendazole sulfoxide, the main metabolite of triclabendazole (6-chloro-5-(2,3-dichlorophenoxy)-2-methylthio-benzimidazole) and to assess the bioequivalence of two formulations of oral suspension containing triclabendazole 50 mg/ml each in 36 healthy sheep. In order to determine the relative bioavailability of the test product with respect to the reference product the study was designed as a randomized, crossover study, with administration of a single-dose, under fasting conditions in each of the two study periods. For the determination of triclabendazole sulfoxide sheep plasma concentrations a rapid, selective high performance liquid chromatography coupled with mass spectrometry (LC-MS/MS) method was developed and validated. The measured plasma concentrations of triclabendazole sulfoxide were used for the determination of bioequivalence between the test product with regards to the reference product. Noncompartmental analysis of the pharmacokinetic data of triclabendazole sulphoxide showed similarity between first-order kinetics of the test and reference product. The relevant pharmacokinetic parameters (Cmax, AUClast, AUCtot) were determined. The mean values for Cmax were 56.0 (+/-17.1) µg/ml for test and 54.4 (+/-20.1) µg/ml for the reference product. The mean values for the AUClast were 1655.6 (+/-443.9) µg/ml x h for test and 1803.3 (+/-750.6) µg/ml x h for reference product. The mean values for the AUCtot were 1702.4 (+/-445.9) µg/ml x h for test and 1847.7 (+/-755.6) µg/ml x h for reference product, respectively. The mean bioequivalence (mean ratio "Test/Reference") for Cmax and AUClast is 1.05119 and 0.969058 respectively. The 90% confidence intervals for the ratio of means of triclabendazole sulphoxide "Test/Reference" are 98.28-112.44% and 87.97-106.75% for Cmax and AUClast, respectively, which lies within the conventional bioequivalence range of 80-125%. The difference between means is not statistically significant for the Tmax of the test and reference products (Friedman and Kruskal Wallis test). It was thus concluded that the test product is bioequivalent to the reference product with regards to the rate and extent the pharmacokinetics of triclabendazole sulfoxide.

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