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Steady-state bioavailability of extended-release Methylphenidate capsule vs. immediate-release Methylphenidate tablets in healthy adult volunteers

A novel formulation of extended-release (ER) methylphenidate hydrochloride that utlizes multiple layers of coatings on microbeads for encapsulation into hard gelatin capsule shells (Aptensio™, MPH-MLR) was evaluated to determine the relative bioavailability vs. immediate-release methylphenidate tablets (IR, Ritalin®) as single and multiple doses in the fed state. A single-center, 4-day, multiple-dose, randomized, open-label, 2-period crossover study design assessed the relative bioavailability of MPH-MLR 80 mg once daily versus Ritalin® IR 25 mg 3 times daily (TID) in 26 healthy adults. Serial blood samples were collected at pre-specified time points over the 4-day dosing period for determination of methylphenidate concentration and pharmacokinetic analyses. Relative bioavailability of MPH-MLR versus Ritalin (75 mg total daily dose normalized to a single dose of MPH-MLR) as a single dose under fed conditions, and at steady state under fed conditions, was determined based on AUC0-t, AUC0-inf and Cmax of methylphenidate. MPH-MLR administration produced a rapid initial peak, a moderate decline until ~5 hours postdose, and a gradual increase until ~7 hours postdose. Cmax was lower for MPH-MLR 80 mg than methylphenidate IR 25 mg on day 1. Exposure was similar with 90% CI limits for the geometric mean ratios of log-transformed AUC0-t that were within the 80%-125% equivalence range. Day 4 partial AUC0-4 (74.49±15.23) for MPH-MLR exceeded Ritalin IR 25 mg 3 times daily (66.01±17.41), and therefore was not bioequivalent. MPH-MLR capsules administered once daily or methylphenidate IR administered TID provides comparable maximum methylphenidate concentrations and systemic exposure in the fed state.

Biography

Akwete Lex Adjei, PhD has a wealth of experience in drug design and drug delivery technology. After receiving his PhD from the University of Texas, Austin, he did his Post-graduate work on complexation of xanthine drugs in non-ideal sovent systems. He has held positions at several pharmaceutical companies and currently is Executive Director of R&D at Rhodes Pharmaceuticals, L.P. He has been the author/co-author of 38 published peer-reviewed articles and 15 books or book chapters and he has almost 50 patents for his work in this area. He is an experienced presenter with more than 25 presentations by special invite.

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