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Steady-state bioavailability of extended-release methylphenidate capsules vs. immediate-release methylphenidate tablets in healthy adult volunteers

A novel formulation of extended-release (ER) methylphenidate hydrochloride that utilizes multiple layers of coatings on beads 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 AUC_{0-t}, AUC0-inf and C_{max} 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. C_{max} 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 AUC_{0-t} that were within the 80%-125% equivalence range. Day 4 partial AUC_{0-4} (74.49±15.23 hr.ng/mL) for MPH-MLR exceeded Ritalin IR 25 mg 3 times daily (66.01±17.41 hr.ng/mL), and therefore was not bioequivalent. MPH-MLR capsules administered once daily and methylphenidate IR administered TID provided comparable maximum methylphenidate concentrations and systemic exposure in the fed state.

Biography

Akwete Lex Adjei has completed his PhD from the University of Texas, Austin and his Postgraduate work on complexation of xanthine drugs in non-ideal solvent systems. He has held positions at several pharmaceutical companies and he is currently an 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 has almost 50 patents for his work in this area.

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