Bioequivalence study of tramadol by intramuscular administration in healthy volunteers

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Abstract

Tramadol hydrochloride (CAS 36282-47-0) is a centrally acting analgesic agent binding to mu opiate receptors. The bioavailability of a new tramadol hydrochloride injection (Limadol) was compared with a commercially available reference product by intramuscular administration in twelve healthy Chinese male volunteers by a standard two-way cross-over trial. Each volunteer received a single 100 mg injection of tramadol HCl in each phase. The bioavailability was compared using the area under the plasma concentration-time curve from time 0 to 30 h (AUC0-30), the area under the plasma concentration-time curve from time 0 to infinity (AUC0-infinity), peak plasma concentration (Cmax), and time to reach peak plasma concentration (Tmax). No statistically significant difference was observed between the Tmax, Cmax, AUC0-30 and AUC0-infinity of the two preparations. It is concluded that test and reference formulations of tramadol hydrochloride are bioequivalent for both the extent and rate of absorption after a single intramuscular injection.