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Comparative bioequivalence, safety and performance evaluation of novel matrix type oxybutynin transdermal patch

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Abstract

Oxybutynin is widely used anticholinergic compound for overactive bladder (OAB) syndrome. When administered orally, high concentrations of metabolite N-desethyl oxybutynin (DEO) elicits side effects like dry mouth, blurred vision and other cholinergic disturbances. Transdermal oxybutynin have an edge over bypassing hepatic metabolism and thereby reducing metabolite formation and related side effects. The aim of proposed research work was to carry out comparative bioequivalence, safety and performance evaluation of developed novel matrix type oxybutynin transdermal patch with marketed patch (3.9mg/day) which was kept as reference formulation.. The test formulations contain different types of chemical permeation enhancer i.e. Oleic acid (fatty acid), Soluphor P (cosolvent), menthol (volatile oil) and dipropylene glycol (plasticizer). A single dose, randomized, crossover pharmacokinetic study was carried out on healthy rabbits for period of 96 hrs. Patch was applied on dorsal side of abdomen. Plasma concentrations of oxybutynin were monitored using validated gas chromatographic method. Skin irritation (erythema, edema), patch adherence and local application site skin reactions were assessed following patch removal. The ratio of C_{max}, $AUC_{0\text{-}96}$, and $AUC_{0\text{-}inf}$ at 90% confidence interval was found to be 0.92, 1.1, 1.2 for oleic acid, 0.86, 1.03, 1.1 for Soluphor P, 1.1, 1.17, 1.3 for menthol and 0.96, 1.19, 1.34 for dipropylene glycol. Wilcoxon signed rank test was used to assess performance of all permeation enhancers. The pharmacokinetic result demonstrates the developed formulations are bioequivalent with reference formulation and also found to be non irritating as well as safe with good adhesion to skin.

Biography

Achyut Khire is Senior Research Fellow working under the guidance of Prof. P. R. Vavia at Department of Pharmaceutical sciences and technology, Institute of Chemical Technology (Deemed University), Mumbai, India. Since 2007, Achyut khire is working in area of transdermal drug delivery systems and pressure sensitive adhesives used in transdermal drug delivery systems. By the date he has filed 2 patent applications based upon developed platform technologies.