bioequivalence
of Loxamine vs Aropax

Can Loxamine and Aropax be considered bioequivalent?

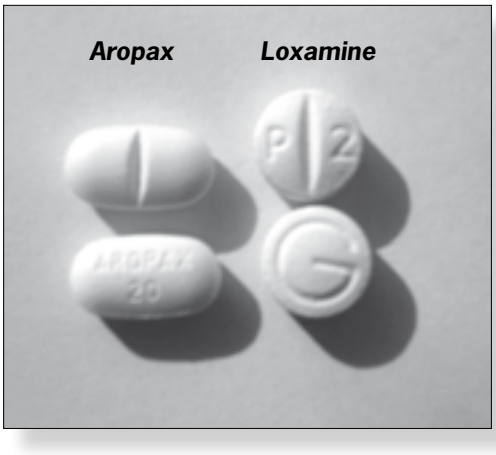
Yes, information received from Pacific Pharmaceuticals shows that the results of the studies on Loxamine are well within the bioequivalence acceptance limits. This means that any variation in bioavailability (AUC, C_{max}) between Loxamine and Aropax is very unlikely to be any different from variations between different batches of the same brand.

Loxamine vs Aropax: Bioequivalence study results

90% confidence intervals for ratios of geometric means

C_{max}	0.978 to 1.117
T_{max}	0.968 to 1.020
AUC 0–t	1.000 to 1.139
AUC 0–infinity	0.998 to 1.136

Loxamine and Aropax are bioequivalent (90% CI's within 0.8–1.25)



Loxamine vs Aropax: Inactive ingredients (excipients)

Both tablets contain 20 mg paroxetine hydrochloride

Aropax tablets also contain; the colouring agent titanium dioxide (white, E171), calcium hydrogen phosphate, hypromellose, sodium starch glycolate (potato starch), magnesium stearate, polysorbate 80 and macrogol 400.

Loxamine tablets also contain; calcium hydrogen phosphate anhydrous, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, purified talc, titanium dioxide and Eudragit 100.

Loxamine contains silica, talc and Eudragit 100 which are not present in Aropax tablets. Silica and talc are widely used, relatively inert compounds used as tablet fillers. Eudragit 100 is a polymethacrylate which is extensively used as tablet film coating. These agents are selected on the basis that they are very unlikely to cause adverse effects but the remote possibility of sensitivity to these excipients cannot be completely excluded.