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Comparative Bioavailability of two piroxicam formulations in relation to their dissolution

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Piroxicam is a nonsteroidal antiinflammatory drug (NSAID) of the oxicam family, which is used in the treatment of rheumatoid arthritis and other rheumatic disorders. Because of its poor water solubility, different products of this drug may be subject to variable absorption and bioavailability. Therefore, the present study was carried out to evaluate the dissolution rate and bioavailability of generic formulation of piroxicam 10mg capsules (Razak Laboratories Co., Iran) compared to the stantard product, Feldene 10mg capsules (Pfizer Co., USA).

12 healthy male voluteers, aged 26-47yrs and body of weight 67-82kg were participated in this study. Each subject received a single oral dose of 20mg piroxicam (as 2 capsules) of either formulation following over night fast in a randomized, cross over way with washout period of 2 months. Blood samples were collected at suitable intervals up to 52h post-administration. The plasma concentration of piroxicam were determined by a HPLC method.

The profile of the dissolution rate of the genenic capsule showed a faster rate of dissolution (t_{50}=4.12min) compared with that of Feldene (t_{50}=10.33min), but the maximum dissolvable drugs were similar in two preprations.The plasma concentration profiles of piroxicam, after administration of either formulation, showed that there were two phases of absorption and two peaks plasma levels were observed. The Cpmax, tmax, t1/2, AUC(0-52) of piroxicam are listed in the following table.

Parameters	Generic cap X(+SE)	Feldene cap X(+SE)	t-test
Cpmax1	1.525(+0.09)	1.465(+0.07)	N.S.
tmax1	1.5(+0.15)	2(+0.13)	P<0.05
Cpmax2	1.287(+0.07)	1.329(+0.07)	N.S.
tmax2	5.6(+0.27)	6(+0.49)	N.S.
t1/2	50.087(+5.5)	55.453(+12)	N.S.
AUC(0-52)	43.34(+2.2)	47.36(+2.27)	N.S.

These results show that these two preprations are statistically comparable, only the Tmax1 values are significantly different i.e. the peak plasma level of piroxicam was achieved earlier in the generic prepration which may be due to its faster rate of dissolution. Therefore, it is concluded that these two preprations have similar bioavailabilities and the generic formulation of piroxicam is interchangeable to the corresponding standard product.