OBJECTIVE OF PRESENT WORK:

Itopride, a novel Prokinetic agent is unique and different from the available Prokinetics because of its dual mode of action and lack of significant drug interaction potential. Thus a Prokinetic drug like Itopride, by virtue of its efficacy and tolerability could be considered as a drug of first choice and a welcome addition to the drug armamentarium for the symptomatic treatment of NUD and other gastric motility disorders including functional bowel disorders.

Meals may have variable and often unpredictable effects on drugs via a range of mechanisms. By understanding and appreciating the clinical consequences of these effects health professionals can provide advice about the appropriateness of ingesting medicines with respect to the times and the composition of meals. The provision of timely and appropriate advice about the possible effects of meals on medicines and the importance (or lack) of the timing of meals and medicines is an important issue impacting on the quality use of medicines.

Also documentation about alterations of Itopride bioavailability by effect of food is poor.

The aim of this study is to compare the pharmacokinetic parameters of Itopride formulation when taken in empty stomach and with high fat meal. So we considered it worthwhile to:

1. Develop a simple, specific and sensitive analytical method for the estimation of Itopride in human plasma.
2. Evaluate the effect of food over the bioavailability of Itopride
3. Observe and compare the safety parameters in both study conditions when the drug is administered to healthy human volunteers.