Formulation and Development of Orodispersible Sustained Release Tablet of Domperidone
M. Repka 1, H. Patil 1, K. Singh 2
1 University of Mississippi, 2 Mumbai University

Purpose
Commercially available Domperidone orodispersible tablets (ODT) are intended for immediate drug release however they have not been formulated for sustained release. The aim of the present research was to develop and evaluate an orodispersible sustained release tablet (ODSRT) containing domperidone, which entails the convenience of an ODT and a controlled release product in one.

Methods
1. Formulation Development of sustained release microparticles: Sustained release microparticles of Domperidone were prepared by an emulsion solvent evaporation method. Optimization was carried out for product and process variables using 2² and 3² factorial designs.
2. Evaluation of Microspheres: Microspheres were evaluated for appearance, particle shape and size, percentage yield, percent drug loading, DSC and SEM.
3. Formulation and evaluation of orodispersible sustained release tablet: ODSRTs were formulated by compression of microspheres along with suitable excipients. A microsphere and excipient blend was evaluated for density, angle of repose, compressibility and Hausner’s ratio. Tablets were evaluated for hardness, friability, disintegration time, uniformity of weight, drug content and in-vitro drug release using a USP type 1 dissolution rate testing apparatus at 100rpm in buffer pH 1.2
4. In-vivo evaluation of orodispersible sustained release tablet:
Pharmacokinetic studies were performed utilizing a crossover design with Wistar rats and the ODSRTs were compared with marketed tablets. Plasma samples were withdrawn at pre-determined intervals and analyzed by a validated HPLC method.

Results
Particle size of the microspheres was optimized to be less than 200 micron to avoid grittiness in the mouth. DSC thermograms of microspheres showed the absence of drug-polymer interaction within the microparticles while SEM confirmed the spherical shape and porous nature. The developed product exhibited a disintegration time of 21sec and matrix-controlled drug release for 9h. In-vivo pharmacokinetic studies in Wistar rats showed that the developed formulation had a prolonged MRT of 11.16h as compared to 3.86h of conventional tablets.

Conclusion
Developed Domperidone ODSRT combines the convenience of fast dissolving orodispersible dosage forms and performance of controlled release delivery systems and can be beneficial commercially.