Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense)*
Lat. Am. J. Pharm. **29** (7): 1199-207 (2010)

Original Article
Received: February 18, 2010
Revised version: March 12, 2010
Accepted: March 14, 2010

Sodium Alginate Microspheres Containing Multicomponent Inclusion Complex of Domperidone

Kailas K. MALI*, Remeth J. DIAS, Vishwajeet S. GHORPADE & Vijay D. HAVALDAR

Department of Pharmaceutics, Satara College of Pharmacy,
Behind Spicer India Ltd., Degaon, Satara, Maharashtra, 415004, India

***SUMMARY*. Sodium alginate microspheres of domperidone for intranasal systemic delivery were developed to eliminate first pass metabolism, improve patient compliance and obtain improved therapeutic efficacy in treatment of migraine, gastro-esophageal reflux and chemotherapy induced nausea and vomiting. Domperidone was encapsulated as ternary inclusion complex with β-cyclodextrin and citric acid to improve solubility. The phase solubility studies were performed in order to select suitable acid and ternary inclusion complex was prepared by kneading method. The complex was characterized by differential scanning calorimetry, X-ray diffraction and Fourier transform infrared spectroscopy. *In vitro* dissolution study was carried out in simulated nasal electrolyte solution, pH 6.4. The microspheres of optimised ternary inclusion complex were prepared by emulsification-cross-linking method and were evaluated for particle size, encapsulation efficiency, equilibrium swelling degree, *in vitro* mucoadhesion and *in vitro* drug release. The effect of various formulation variables such as drug loading, polymer concentration, cross-linking agent concentration and cross-linking time on microsphere characteristics were studied. The microspheres size range was 57.63-65.3 μm, whereas the percentage drug encapsulation was within the range 15-50 %. All microspheres showed good bioadhesive properties. The formulation variables influenced the drug release profile. The treatment of *in vitro* release kinetics with kinetic equations indicated that the domperidone release followed Higuchi's matrix model.**

KEY WORDS: β-cyclodextrin, domperidone, microspheres, solubility, ternary inclusion complex.
*Author to whom correspondence should be addressed. E-mail: kailas_mali@rediffmail.com