FORMULATION AND *IN-VITRO* EVALUATION OF CONTROLLED POROSITY OSMOTIC PUMP TABLET OF DOXOFYLLINE

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ABSTRACT:

Introduction:

Oral route is a convenient route for the administration of drugs because of ease of administration and low cost and good patient compliance. But conventional drug delivery system does not control the release of drug and provides immediate release of drug. Once daily controlled release preparation is often desirable. However, drug release from oral controlled release dosage forms may be affected by pH, gastric motility, and presence of food. One practical approach with a potential to overcome these disadvantages is the Osmotic Drug Delivery System (ODDS). Osmogens are used extensively in the fabrication of Osmotic Drug Delivery Systems which utilizes osmotic pressure for prolong and controlled delivery of drugs. Controlled porosity osmotic pump (CPOP) is a Single chamber Oral Osmotic pump tablet in which membrane contains water soluble leachable pore forming agents. The delivery system comprises a core tablet with drug and osmogens surrounded by a Semi- permeable membrane in which water soluble pore forming additives are dispersed throughout wall of the membrane drug release is achieved through the pores which are formed in the semi permeable wall *in -situ* during the operation. Drug release from these systems is independent of pH and hydrodynamic conditions of GIT and release characteristics of delivery system. **Aims &Objectives:** The aim of research work focused on the formulation and evaluation the Controlled Porosity Osmotic Pump Tablets of Doxofylline with an objective to achieve zero-order release and to reduce dose frequency .**Materials and Methods:** Sodium chloride, Mannitol as Osmogens, and Cellulose Acetate as Semi-permeable membrane, Sorbitol, and PEG 400, 6000 as pore-forming agents, Di-butyl phthalate as Plasticizer, Acetone: methanol as coating solvents respectively.

Methods: Core tablets of doxofylline were formulated using polymer HPMC K4M in different polymer: osmogens ratios by dry granulation technique and NaCl, Mannitol as Osmogens respectively. The formulated tablets were evaluated by Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry(DSC), Micromeritic Properties, Post Compression parameters, then semi permeable (cellulose acetate2.6%) coating was done with different levels of pore forming agents. Coated tablets were evaluated for the physical properties like thickness, hardness, weight variation friability and *in- vitro* drug releases studies, kinetic models are used to assess the *in- vitro* drug release and mechanism of drug release and Scanning electron Microscopy (SEM) were performed. **Results& Discussion:** Among the developed formulation F6 batch showed 98.50 ± 0.64 % drug release at 24 hr. The results of optimized formulation was found to exhibit zero order kinetics independent of the pH and agitation intensity, but depended on the osmotic pressure of dissolution media which indicates the mechanism of drug release was due to osmotic pressure.SEM study showed the formation of pores in Semi-permeable membrane. **Conclusion:** CPOP tablets of doxofylline coated with cellulose acetate had developed and effect of different formulation variables were studied to optimize release profile. The desired release profile was obtained by optimizing amount of osmotic agent and osomoploymer ratio. This system is alternative to conventional osmotic delivery pump as the sophisticated laser drilling technique is not required.