CHAPTER 2. AIM and HYPOTHESIS OF PRESENT WORK

The goal of a present work was to design ideal drug delivery systems, which would produce a constant release of drug from the delivery system and reduce dosing frequency. In addition they should

- Maintain steady state plasma concentration of MH
- Provides controlled drug release for longer duration of time
- Reduce the dosage frequency
- Enhance patient compliance
- Reduce the treatment cost
- Reduce concentration related side effects

The specific research objectives of present work include:

1. Development and validation of spectrophotometric analytical method for MH.
3. To design, develop and characterize oral drug delivery systems of MH to achieve target profiles with following approaches:
   - Monolithic matrix tablet using novel herbal matrix excipient
   - Porosity Controlled Osmotic Pump (PCOP)
   - Tablet in Tablet system (TITs)
   - Solid Dispersion Tablet (SDT)
   - Matrix Molded Tablet (MMT)
   - Oral In Situ Depot System (OISDS)
4. To perform short term stability study for all optimized formulations as per ICH guidelines.
5. To understand the drug release kinetic mechanism for these controlled release formulations.
6. To perform in vivo study of best formulation screened based on in vitro evaluation.
7. To establish invivo-invitro correlation (IVIVC) for the selected formulation.
HYPOTHESIS

Many of controlled delivery systems utilize hydrophilic, polymeric matrices that provide useful levels of control to the delivery of drugs. Such matrices do not provide adequate control over the drug release rate, but instead provide a release pattern that approximates square-root-of-time kinetics in which the total amount of drug released is approximately proportional to the square root of the elapsed time. With this release pattern in an aqueous medium, much of the drug in the matrix of many of these formulations is released into an aqueous medium within the first hour. The benefits of a constant release rate with regard to prolonging therapeutic efficacy while minimizing side effects are well established. It is well known that a nearly constant release rate that simulates zero order kinetics provide consistent drug release. Based on physicochemical properties, pharmacokinetics parameters and clinical need of MH it was hypothesized to achieve nearly zero order release rate from developed formulation (Figure 1).

Figure 1: Desired drug release profile of water soluble drug (MH) from optimized modified release drug delivery system