1.0 ABSTRACT

Oral route is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. The main problem with oral dosage form is difficulty in swallowing solid dosage form especially pediatric and geriatric patients. The goal of present work is to design an oral dosage form for pediatric and geriatric. The present investigation was undertaken with the objective to design, develop and characterize mouth dissolving film and oral soft gel for three different categories of drugs having different dose, granisetron hydrochloride (2mg/dose-very low dose), linezolid (100mg/dose-high dose) and memantine hydrochloride (10mg/dose-low dose) for pediatric and geriatric patients.

Preliminary trials to selection of polymer plasticizer and sweetener for MDF and placket barmen design for screening variable were conducted. Experimental design and desirability function were used for optimization of polymer and plasticizer concentration. All experimental design formulations were evaluated for weight, thickness, drug content, %moisture loss, pH and folding endurance. Stability study RH was conducted at 40°C and 75% for all optimized batch and based on results of all optimized batch best optimized formulation was selected. MDF of linezolid and memantine hydrochloride was prepared and evaluated using the same optimized polymer and plasticizer concentration.

Initially based on preliminary trials, carbopol and gellan gum was selected for preparation of oral soft gel of linezolid. Oral soft gel of linezolid containing carbopol as gelling agent was optimized by using different concentration of carbopol. Oral soft gel of linezolid containing gellan gum as gelling agent was optimized using an experimental design. Formulation of linezolid oral soft gel was evaluated for physical appearance, pH, syneresis (Separation of fluid), viscosity, in-vitro dissolution at 15min and at 30min, drug content and pH. Stability study was conducted at 40°C and 75% RH for both optimized batch. Based on results of stability study, gel prepared using gellan gum was selected as best optimized formulation for linezolid. Oral soft gel of granisetron hydrochloride and memantine hydrochloride was prepared using same optimized concentration of gellan gum used for linezolid and evaluated.

Comparative evaluation based on stability and dissolution study between mouth dissolving film and oral soft gel of granisetron hydrochloride, linezolid and memantine
hydrochloride were conducted. Based on result, mouth dissolving film of granisetron hydrochloride, oral soft gel of linezolid and mouth dissolving film of memantine hydrochloride was selected as best dosage form. Best formulation were evaluated for SEM study (for film only), In-vivo comparative pharmacokinetics, in-vivo taste acceptability study in human volunteers, microbial testing and texture analyzer study (for gel only).

From above presented study, it can be concluded that for low dose drug- mouth dissolving film and for high dose drug- oral soft gel can become best, accurate and more patient compliance alternative dosage form as compare to conventional tablets and capsules dosage form.

**Key words:** Mouth dissolving film, granisetron hydrochloride, RP-HPLC, oral soft gel, linezolid, memantine hydrochloride.