

Standardization of aqueous extract from *Malva sylvestris* and preparation an oral colon specific formulation for treatment of Ulcerative Colitis

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Abstract

Introduction: *Malva sylvestris* is one of medicinal plants from Malvaceae family. According to some important Iranian traditional medicine's references (ITMR) all parts of this plant can be used for treatment of "Zahir" that this disease has similar signs and symptoms to Ulcerative Colitis (UC). UC is one of the common types of Inflammatory Bowel Disease (IBD) which mostly affects distal colon and rectum in many new cases each year. Because of low efficacy and high adverse effect of today's drugs, many refers of ITMRs, high frequency in Iran and our team's previous study of several extraction from this plant on UC induction in mice, we decided to use aqueous extraction to prepare an oral colon specific formulation.

Methods and Results: The fresh plant was collected from North of Fars province. Hydro extraction was done with maceration route in the refrigerator and out of light and then the concentrated extraction was lyophilized. Polysaccharides extraction was done with absolute acetone and poly phenolic compounds were extracted with n-hexane and ethyl acetate. For all of total sugar evaluated with Phenol-Sulfuric acid method. Also Gallic acid and Folin-Ciocalteu reagents were used for determination of total phenolic compounds. Twelve formulations prepared and *in vitro* evaluations were done based on US Pharmacopoeia. Disintegration time test, dissolution time test, hardness, weight variation, content uniformity and release test were performed on tablets. Yield of total extraction and polysaccharides extraction were 10.83% and 9.6% W/W. Be calculated 0.18 mg poly phenolic compounds in each 1 g of lyophilized extraction. Other Pharmacognosy's tests (Linearity, intra and inter day accuracy and precision) and pharmaceutical tests (Hardness, weight variation and content uniformity of tablets) were in the acceptable range. Tablets coated with Eudragit S100 (E) 2% solution exhibited 7.3% release after 2 hours, 42.33% after 6 hours and 96.21% after 10 hours.

Conclusions: Tablets that used *Malva sylvestris* as active pharmaceutical ingredient and prepared by direct compression method and coated with E 2% solution, showed the most suitable results for clinical trials in UC cases.

Key words: *Malva sylvestris*, Ulcerative Colitis, Aqueous extraction, Poly phenolic compounds, Colon specific formulation.