Formulation and evaluation of physicochemical properties of the orally dissolving film of donepezil

Shokouh Banani Rad1, Zahra Jafari Azar, Ramin Asgharian

1-Department of Pharmaceutics, Pharmaceutical Sciences Branch, Islamic Azad University (IAUPS), Tehran, Iran

Abstract: Alzheimer disease is the most common cause of dementia that slowly destroys memory and thinking skills. Donepezil hydrochloride is a reversible inhibitor of the enzyme acetylcholinesterase which is used to treat mild to moderate Alzheimer disease. Orally dissolving film is relatively a new dosage form which is prepared by hydrophilic polymers rapidly dissolved on tongue or buccal cavity. The aim of this study was formulation of oral dissolving films (ODF) containing Donepezil for the treatment of Alzheimer disease, which is dissolved in oral cavity in the shortest time. ODF is preferable than conventional tablets for patients with dysphagia. ODFs have rapid onset of action, improve bioavailability and helpful for geriatric patients with swallowing dysfunctions.

In this study, ODF of Donepezil was prepared by solvent evaporation using HPMC 6CPS (Hydroxypropyl methylcellulose), PVP (Polyvinylpyrrolidin) k30, Carbomer 934, HPMC 4000cps, PG (Propylene Glycol), HPMC 50 cps, PEG 400(Polyethylene Glycol), Glycerin with different percents and various combination of each group. After formulation, different physicochemical tests were performed as follows. Weight, thickness, disintegration time, assay and also dissolution time were done on all the formulations.

The best formulation was carried out in one third of PVP and HPMC 6cps containing PG in 20 percent. The formulation which released 80 percent of Donepezil Hydrochloride in 5 minutes was chosen. We hope to have the opportunity to scale it up.

Keyword: Alzheimer, donepezil, ODF (orally dissolving film)