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Development of Solid Self Emulsifying Drug Delivery System of Clotrimazole Using Foam-Mat Drying Technique

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Introduction: Clotrimazole is an antifungal agent that commonly used in the treatment of fungal infections. But it is a poorly water-soluble drug. There exist many attempts to enhance its dissolution and bioavailability such as complexation, cosolvency and solid dispersion are recorded. In recent years much attention has been focused on self-emulsifying drug delivery systems to improve oral bioavailability of poorly water-soluble drugs. However, there is a few limitations associated with this delivery system, including stability, manufacturing methods, interaction of the fill with the capsule shell, and storage temperature. So that, the researches focused on solid SEDDS area were increasing to overcome these problems. These solid SEDDS were prepared by extrusion/spheronization method, wet granulation in a high shear mixer and spray drying. However, in this study we intend to prepare solid SEDDS by foam-mat drying technique with foaming agents and inert solid carrier. **Material and method:** SEDDS of clotrimazole consisted of polysorbate 80, oleic acid and medium chain triglyceride (MCT) which contained clotrimazole 40 mg/mL. Albumin powder, soybean protein and hydroxypropyl methylcellulose 4000 (HPMC 4000) were used as the foaming agent and maltodextrin was a diluent. Foaming agents and solid carrier were mixed with liquid SEDDS of clotrimazole by homogenizer until foam was formed and then dried in hot air oven or vacuum dryer at 60 $^{\circ}$C for 24 hours. Appropriate dried foam was mixed with the diluents and filled in capsules. In vitro dissolution study was carried out by dissolution apparatus II using 0.1 N HCl as a medium and drug dissolved was quantified using HPLC method. Solid state characterization and thermal property were performed using powder X-ray diffraction (PXRD) and differential scanning calorimeter (DSC), respectively. **Result:** The formula contained liquid SEDDS 20% and 10% with 10% albumin powder or soybean protein and dried in hot air oven at 60°C for 24 hours gave suitable dried products with no interaction of clotrimazole and foaming agent. The dissolution of foam-mat dried formulation consisted of SEDDS 20% and 10% with 10% soybean protein demonstrated about 48.93% and 18.91%, respectively. Those with 10% albumin showed 8 and 12%, respectively. **Conclusion:** The foaming agent used for foam-mat drying technique of SEDDS of clotrimazole was soybean protein. It was mixed with liquid SEDDS by homogenizer to produce stable foam and dry in hot air oven at 60°C for 24 hours. The foam-mat product gave the faster drug release in which compared with the physical mixture due to its amorphous character.

Keywords: Solid self emulsifying drug delivery system, Clotrimazole, Dissolution, Foam-Mat Drying

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