

Preparation and characterization of a solid self emulsifying drug delivery system (SSEDDS) for loratadin by extrusion-spheronization.

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Background and Aims: Recently the liquid self emulsifying drug delivery systems (SEDSS) have shown dramatic effects on improving oral bioavailability of poorly soluble drugs. The main purpose of this study was to prepare a solid form of lipophilic-based self emulsifying drug delivery system by extrusion-spheronization. The liquid SEDSS are generally prepared in a soft or hard gelatin capsules and suffers from high production costs, low drug incompatibility, low stability, drugs leakage, precipitation and capsule ageing. Therefore incorporation of SEDSS into solid dosage form is desirable to get together the advantages of SEDSS and solid multiparticulate systems.

Methods: The SEDSS was consisted of liquid paraffin, capriole, span 20, transcitol and loratadin as a poorly soluble drug. A multilevel factorial design was used to formulation of SSEDDS, 20 and 30% liquid SEDSS was mixed with lactose, microcrystallin cellulose (40%) and silicon dioxide (0, 5 and 10%) as fillers or absorbents, and sodium crosscarmelose (0, 5 and 10%) as disintegrant. The resulting wet mass transformed into pellets by extrusion-spheronization. The pellets were dried and characterized for size distribution (sieve analysis), aspect ratio and sphericity (image analysis), mechanical strength (friability test), droplet size (laser light scattering) and drug release rate (dissolution test).

Results: The study shows that increasing the amount of silicon dioxide lead to improve pellets sphericity but increase the mean dissolution time (MDT) and disintegration time of the pellets. Crosscarmelose cause faster pellet disintegration and decrease their MDT. The percent of SEDSS had no considerable effect on MDT, sphericity or disintegration time. Mechanical strength of pellets did not affected by studied factors, significantly. But total friability of pellets containing 30% SEDSS was higher than those with 20% SEDSS.

Conclusions: Overall results revealed the feasibility of preparing desirable self emulsifying pellets containing loratadin with fast disintegrating and fast dissolving properties.

Keywords: Self-emulsifying system; Loratadin; Extrusion-spheronization