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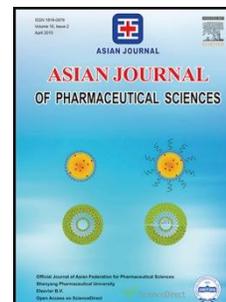
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Succinylated soybean protein as novel excipient for matrix sustained release microspheres

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Many native proteins possess limited functionality, and modification such as succinylation is often performed to expand the range of functional properties available for pharmaceutical dosage form. Succinylation could be useful for modulating protein-based system swelling and drug delivery properties especially for sustained controlled release dosage form like microsphere. A well designed controlled drug delivery system can overcome the problems of conventional drug therapy and gives better therapeutic efficacy of a drug. Microspheres are also undersigned as novel controlled drug delivery system having particle size less than 200 μm .

The aim of this research was succinylated soybean protein (SSP) that could be used as excipient matrix for sustained release microspheres containing propranolol hydrochloride as a model active pharmaceutical ingredient.

Soy protein chemical modification was carried out as follows. Soy concentrated protein was dispersed in distilled water for 2 h at a concentration of 5% w/v, and stirred 2 hours with a speed of 1000 rpm. Succinic anhydride at amount 100 % b / b to protein was dissolved in ethanol 96%, and then added gradually to the soy concentrated protein with constant stirring and the pH was maintained between 8 and 8.5 with 5M NaOH. The reaction was completed when the pH of the protein solution stabilized. Excess succinic anhydride was removed with ethanol 96%, and suspension of soy protein succinate was neutralized with NaOH 0.5N then dried with oven at 45-45°C. After that the product was analyzed included; degree of succinylation, chemical interaction between soybean protein and succinic anhydride by FTIR spectroscopy, solubility index in aqueous medium at pH 1.2 and pH 7.5, swelling index. Succinylated soybean protein was used as excipient in formula microsphere with propranolol HCl as a model active pharmaceutical ingredient.

Succinylated soybean protein had degree of succinylation $35.74 \pm 0.38\%$. Chemical interaction showed peak in wave at numbers 1653 cm^{-1} on IR spectrum which was indicating formed amide carbonyl group; had solubility index 0.21 ± 0.010 gram/100 ml in distilled water at pH 1.2 and 0.35 ± 0.003 gram/100 ml and pH 7.5, and had swelling index $33.21 \pm 2.04\%$ at pH 1.2 and $66.36 \pm 2.12\%$ at pH 7.5. Sustained release microspheres containing propranolol hydrochloride were made by using spray dryer and obtained microspheres had particle diameters 11.54-16.79 μm , had yield values 36.46-58.91%, and had encapsulation

efficiency values 95.75-99.81%. The formula that composition 0,5% propranolol hydrochloride and 2% SSP wasqualify as drug sustained release up to 12 hours.

Keyword: Microspheres; Soybean Protein; Succinylation; Sustained Release.

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