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Original Article

Salbutamol sulphate-ethylcellulose microparticles: formulation and in-vitro evaluation with emphasis on mathematical approaches

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Abstract:

Background and the purpose of the study: This study reports the laboratory optimization for the preparation of salbutamol sulphate-ethylcellulose microparticles by a non-solvent addition coacervation technique through adjustment of the ratio of salbutamol sulphate to ethylcellulose. The variation of drug release between the microparticles and tableted microparticles was also investigated.

Methods: In vitro release profiles of developed microparticles and tableted microparticles were studied using USP XXIV dissolution apparatus I and II, respectively, in 450 ml double distilled water at 50 rpm maintained at 37°C.

Results: White microparticles with no definite shape having good entrapment efficiency (96.68 to 97.83%) and production yield (97.48 ± 1.21 to $98.35 \pm 1.08\%$) were obtained. In this investigation, initial burst effect was observed in the drug release behavior. The rate of drug release from microparticles decreased as the concentration of polyisobutylene was increased from 6% to 12% during microencapsulation. The release pattern of tableted microparticles was affected significantly ($p < 0.05$) by the addition of hydroxy propyl methyl cellulose (HPMC) as excipient and insignificantly ($p > 0.05$) by the type of dissolution media and stirring speed. Tableted microparticles showed good stability and reproducibility. Ethylcellulose was found to be compatible with salbutamol sulphate. The drug release from all formulations was best fit to Higuchi's equation and the mechanism of drug release was anomalous diffusion from all formulations.

Conclusion: The results of this study suggest that by using ethylcellulose it is possible to design a single-unit, sustained-release oral dosage form of salbutamol sulphate for indication of twice a day.

Keywords:

Salbutamol Sulphate . Ethylcellulose . Non-solvent addition Coacervation . Dissolution

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