Next Generation Nebuliser Formulations

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Background and Rationale

Microemulsions have been proposed as vehicles for formulating poorly soluble drugs. This study aims to develop a Fluticasone propionate (FP) microemulsion that exhibits advantages over the commercially available suspension, Flixotide. The most promising prototype from preliminary studies on a steroid nanoemulsion (1) was chosen for optimisation by reformulating with crodamol (instead of isopropyl myristate) as the oil phase for the microemulsion. It was postulated that this, in addition to increasing the surfactant concentration, would increase the solubilising capacity. The new formulation was prepared using crodamol as the oil phase and Tween 80 concentration was increased from 10% w/w to 25% w/v to provide the necessary solubilising capacity. These formulations were evaluated for respirability and compared to Flixotide.

Results & Discussion

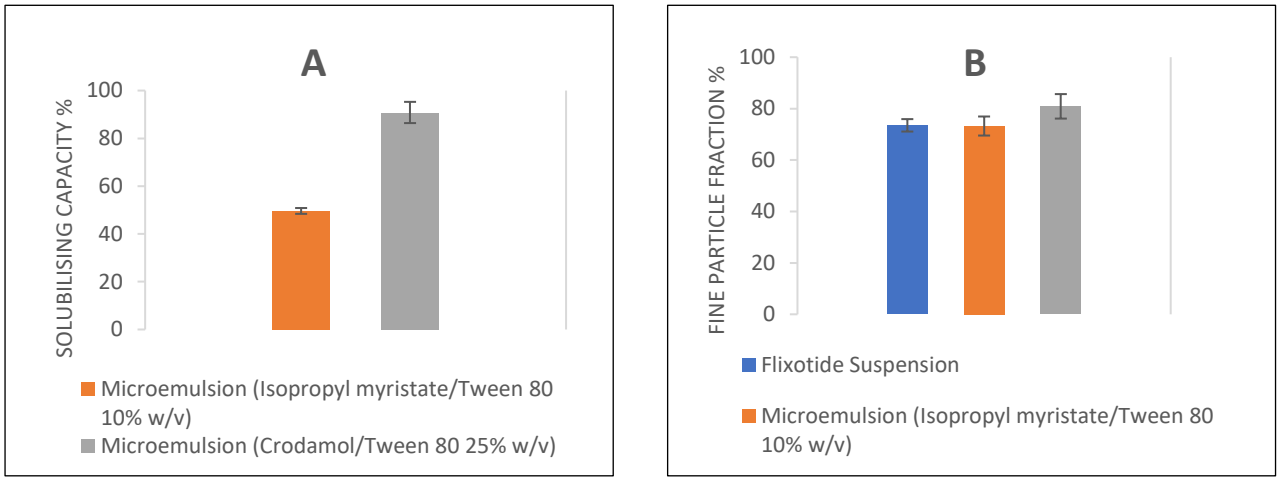

Figure. A: Solubilising capacity of microemulsions with different oil phase/surfactant concentration B: Fine particle fraction determined using NGI apparatus. Data represent = mean and SD (n=3).

The solubilising capacity of the microemulsion formed was evaluated and it was found that it increased significantly from 49% to > 90%. This improvement in solubilising capacity was attributed not only to the use of crodamol as the oil phase but also to effect of increased surfactant concentration stabilising the microemulsion structure and thus providing a more solubilising environment for FP molecules in the oil phase. There was also a small but significant improvement ($p<0.005$) in fine particle fraction suggesting a higher number of aerosol particles in the respirable range.

Ongoing work.

- A fuller evaluation of the aerodynamic performance of the crodamol microemulsion in comparison to commercial suspension, Flixotide.
- Compare the performance of the microemulsion formulation versus suspension using an *in vitro* dissolution assay being developed for this purpose.

Reference.

1. Amani A et al. Evaluation of a Nanoemulsion-Based Formulation for Respiratory Delivery of Budesonide by Nebulizers. AAPS PharmSciTech. 2010 Sep 24;11(3):1147–51.