

## Efficient taste masking through high shear coating with lipid excipients

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### Introduction:

Solid lipid excipients can be used as taste masking agents in hot melt coating in a fluid bed coater. The lipid is melted and sprayed onto the drug particles forming a lipid film which acts as a physical barrier between the bitter drug and the taste receptors in the oral cavity. The process can be considered time and material efficient and 'green' since the coating time is short, solvents are not required and 100% of the coating material is applied. However, heating protocols for the feeding tubes and spray nozzle may be considered complicated. In this study we evaluated an alternative taste masking process using a high shear coater (Diosna P1) without external heating.

### Aims:

Using KCl as model drug, demonstrate that high shear coating is a simple process suitable for taste masking.

### Methods:

The heat required to induce lipid melting was generated by inter-particulate friction. A surface response experimental design was employed to investigate optimal process parameters. The drug was considered to be successfully coated when the release of individual drug particles was below the bitter taste detection threshold of 0.02M (1) corresponding to 1.5mg/mL. Drug release was conducted for 5 min in 3mL of demineralized water using an electrical conductivity meter. Glyceryl distearate (Precirol® ATO 5) was used as lipidic coating material (20% w/w) and potassium chloride (KCl, 80% w/w) as model drug.

### Results:

Microscopic images of KCl particles before coating showed transparent drug crystals, which turned opaque for coated KCl particles. This suggests at least partial coating. Six out of thirteen process parameter combinations provided drug release below the detection threshold. Efficient particle coating for taste masking depended on all three parameters: impeller speed, chopper speed and coating time. Best results were obtained when combining medium impeller with low chopper speed and short coating time, or low impeller with high chopper speed and medium coating time.

### Conclusions:

The study showed that high shear lipid coating is a promising coating technology to mask the unpleasant taste of individual drug particles. The use of such basic equipment can accelerate product development and make taste masking an efficient and simple approach. KCl, a bitter salt with need for oral age appropriate formulations, was coated with glyceryl distearate, a lipid excipient having precedence of use in pediatric hard gelatin capsules of acetaminophen and plant extracts (Doliprane 500 mg capsules, Varitrat capsules).

### Keywords

High shear coating – taste masking – Precirol® ATO 5 - pediatric