**INTRODUCTION**

The administration of medicines to children poses a challenge to many parents and health care professionals; this is linked to the lack of age-appropriate oral formulations. Strategies such as crushing tablets or mixing medicine with food and drinks are used to aid this problem, yet these strategies can affect medicine efficacy, dosing accuracy and bioavailability.

**Multiparticulate formulations** can be used as medicines; they offer the potential of coating to taste-mask coupled with flexible dosing. However, there is limited knowledge on how mouthfeel can affect the palatability and overall acceptability of multiparticulate products.

We conducted an ethically approved study that was designed to compare participant-reported outcomes to researcher observations in the assessment of acceptability of placebo multiparticle formulations.

**MATERIALS AND METHODS**

Children (aged 4-12 years) sampled three unique 500mg samples of neutral tasting placebo multi particulate products. The sample was administered on a medicine spoon with approximately 3ml spring water. Samples available ranged in size from 200 to 700μm and were available as coated (c) or uncoated (u) versions of each size.

After each sample intake participants had free access to water to clean their palate; the volume of water consumed was recorded.

A questionnaire was completed immediately after sample intake which included a 5-point hedonic facial scale (Chen et al., 1996) to assess grittiness, sample volume, mouthfeel and taste (A). Voluntary feedback from the participant was also optional.

![Consent from parent/carer and child](image1)

Consent from parent/carer and child

![Child completes questionnaire after each test sample](image2)

Child completes questionnaire after each test sample

![Researcher observes child](image3)

Researcher observes child

Participants’ facial expressions and behaviours were recorded prior to, during and post intake using a 12-point tick chart based on the behavioural observations, of children tasting food (Zeinstra et al., 2009) (B). The following observations were used as indicators of unacceptable mouthfeel:

<table>
<thead>
<tr>
<th>Facial Expressions</th>
<th>Behaviours (prior to / after)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes squeezed/shut</td>
<td>Voices disgust</td>
</tr>
<tr>
<td>Brow bulge</td>
<td>Resistance</td>
</tr>
<tr>
<td>Nose wrinkled</td>
<td>Spits out/vomits</td>
</tr>
<tr>
<td>Pursed lips</td>
<td>Refusal</td>
</tr>
</tbody>
</table>

**RESULTS**

71 participants aged 4-12 years were recruited to the study (mean age = 7 years). The sample was refused on 7 out of 213 occasions; furthermore there were 9 instances where following administration of the sample, it was spat out by the participant. Therefore a simple measure of acceptability as used in other studies, where swallowing of the dosage form, even with chewing, was measured as an acceptable formulation [3-5] suggested that in this study the overall acceptance rate was 92.5%.

Researcher observations demonstrated that many children exhibited facial expressions during administration of the multiparticulate products but, no trends in the frequency of these behaviours based on the size of the multiparticulates being sampled were found (C). There were 20 instances (out of 197) where the participants voiced disgust following the sample which was lower than anticipated.

![Typically acceptance on a hedonic scale is neutral to positive face.](image4)

Typically acceptance on a hedonic scale is neutral to positive face. The results shown in (D) highlight that the hedonic participant-reported outcomes for the multi particulates ranged from 30-64% for the range of samples assessed. There were no trend to suggest that there was an optimum particle size (p = 0.306). In addition, no significant differences in palatability preferences of coated and uncoated particles were found.

![Percentage of population giving that score](image5)

Percentage of population giving that score

(D) Hedonic score answers shown as percentage scores of participant responses when asked about the sample grittiness

Overall, only 30% of children stated that they would be willing to take this every day if it were a medicine.

**CONCLUSIONS**

This is the first study to evaluate the mouthfeel of multi particulates in children. The ability to swallow the complete dose of multiparticulates (500 mg) was 92.5% in children and there were no differences in acceptance of the particles based on the size range investigated.

The scale used was well understood by children, however it is apparent that they seemed to measure liking the product and not acceptability. Novel materials are complex and perhaps multiple administrations are required to accurately measure acceptability. Further investigation, using a different vehicle or a dosing device to administer the multi particulates may improve the palatability of this formulation and participant reported outcomes.

**REFERENCES**