Palatability and acceptability of multiparticulate formulations: adults vs. children comparison

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Background knowledge

Evaluation of **palatability and patient acceptability** should be an integral part of the pharmaceutical development studies.

Patient acceptability: “The overall **ability** and **willingness** of the patient and its caregiver to use the medicine as intended.”

**Multiparticulate formulations** offer advantages over conventional solid and liquid dosage forms for paediatrics.

However, little is known about palatability and patient acceptability of multiparticulate formulations.
Study aims

To develop methodology for palatability and acceptability testing

To generate knowledge towards a standardised methodology for assessment of palatability and patient acceptability

To evaluate multiparticulate formulations in adults and children

To assess the potential of multiparticulates for the administration of medicines to children
Study design

- **Children 4-12 years**
  - Sample 1: 5-10 min break
  - Sample 2: 5-10 min break
  - Sample 3: 5-10 min break

- **Adults 18-40 years**
  - Sample 1: 5-10 min break
  - Sample 2: 5-10 min break
  - Sample 3: 5-10 min break

- **Particle size (µm)**
  - 200-355
  - 350-500
  - 500-710
  - 700-1000

- **Coated/Uncoated**
  - 500 mg sample with 3 ml water

- **Locations**
  - Birmingham
  - London

- **Universities**
  - University of Birmingham
  - UCL
Outcome measures

Researcher observations
(Before, during and after sample intake)

1. % volunteers able to swallow the complete dose of multiparticulates

2. Negative facial expressions and behaviours towards the samples

<table>
<thead>
<tr>
<th>Facial expression</th>
<th>Negative behaviours</th>
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</thead>
<tbody>
<tr>
<td>Eyes squeezed/shut</td>
<td>Voices resistance (prior)</td>
</tr>
<tr>
<td>Brow bulge (frown)</td>
<td>Voices disgust (post)</td>
</tr>
<tr>
<td>Nose wrinkle</td>
<td>Cries/screams</td>
</tr>
<tr>
<td>Pursed lips</td>
<td>Vomits</td>
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Subject-reported outcomes
(Immediately after sample intake)

3. Hedonic scales: grittiness, volume, mouthfeel, taste

4. If this was a medicine, would you be willing to take this every day?

   Yes ☐  No ☐

5. Text box for open-ended responses about samples
Overall acceptability of multiparticulates

Adults

61 participants (18-37 years; median = 22)
3 samples each → 183 administrations

Children

71 participants (4-12 years; median = 7)
3 samples each → 213 administrations

Wide acceptance of multiparticulates in both populations
Facial expressions show some level of discomfort
No negative behaviours were observed in adults
No trend between observations and particle size

Consistently higher level of discomfort than adults
20 occasions voiced disgust, 9 voiced resistance
No trend between observations and particle size
Subject-reported outcomes

Samples were described as “tasteless” but the “gritty” feeling in the mouth was a limitation for palatability and acceptability. Samples were often described as “sandy”
Effect of formulation factors

**Adults**

- Preference for smaller sizes ($p = 0.039$)

**Children**

- No particle size preference ($p = 0.306$)
Conclusions

Results of this study highlight methodology barriers to evaluate palatability and patient acceptability of pharmaceutical formulations.

Further studies are needed to generate knowledge towards standardised methodology for palatability and acceptability testing.

The ability to swallow the complete dose of multiparticulates (500 mg) was 92.5% in children and 100% in adults; however, the willingness to take the sample everyday was only 29.6% and 73.8%, respectively.

Textural aspects (i.e. grittiness) were the main barrier to palatability; in this regard adults preferred smaller particles (<700 µm) whereas children showed no size preference.
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Thank you for listening!