**Objective**

Orally disintegrating tablets (ODTs) are often prescribed for older people and children whose swallowing abilities are poor (easy desintegration in mouth without need for water). When ODTs disintegrate, the concentration of dissolved drug in the mouth is greater than with conventional tablets. Thus, taste masking is an important issue for ODTs.

Famotidine orally disintegrating tablet (FODT) was the first ODT on the Japanese market and currently, after expiry of the patent, there are eight generic forms of this product on the market. In the present study [1], the differences of taste between the original orally disintegrating tablet and the eight generic versions of FODTs were studied.

**Method, Experimental Conditions & Samples**

**Method & Samples**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Description</th>
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<tr>
<td>OP</td>
<td>Original product</td>
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<tr>
<td>A to H</td>
<td>Eight generic medicines</td>
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The taste of orally disintegrating tablets was analyzed by means of human sensory panel tests and using an electronic tongue. The aim was to compare not only the bitterness of the various tablets but also the overall taste of drug products, so as to assess their palatability.

**Sensory Panel Analytical Conditions**

- **No. of trained panelists:** 11
- **Scoring scale:** 1 (low) to 5 (strong)
- **Time for sample in mouth:** 30 s
- **Time between 2 samples:** 20 min

The panel was trained using solutions of quinine sulfate as a standard for bitterness, and sucrose solutions as a standard for sweetness.

**E-Tongue Analytical Conditions**

Ten tablets of each product (corresponding to 100 mg famotidine) were placed in a stainless-steel mesh basket. The baskets were placed in a 100-ml beaker which was put into a thermostatically controlled shaking water bath (37±0.5 °C at 25 rpm) containing 100 ml of distilled water. After 10, 20, 30 and 60 s, the suspensions were filtered under reduced pressure. These solutions (from all four time points) were used for taste sensor measurement.

In the overall taste analysis, standard solutions of pure quinine sulfate and aspartame at various concentrations were also analyzed with an aim to visualize respectively bitterness and sweetness axis.

**Working Principle of Electronic Tongue Compared to Human Taste**

![Working Principle of Electronic Tongue Compared to Human Taste](image)

1. 16 or 48 position Autosampler (80 or 15 mL beakers)
2. Array of 7 electrochemical sensors (cross-selective & partially specific) + 1 reference electrode → potentiometric measurement
3. Electronic unit for acquisition & autosampler control
Sensory Panel Results

Figure 1 shows the scoring results obtained by the sensory panel. The bitterness score of the original product was 1.0, the lowest of all the FODTs used in the present study. The bitterness intensities of the generic products A, E and F showed significantly stronger bitterness compared with the original product, while no significant differences in sweetness scores were found between the original and the generic products, which was significantly less sweet than the original product.

Electronic Tongue Results

A Principal Component Analysis (PCA) was carried out on the E-tongue measurements to map an overall taste profiling of all FODT solutions. The original product was located near the area of sweet standard solutions, at some distance from the generic products.

For a detailed comparison, the Euclidean distances were calculated for all the generic products by comparison with the original product. These distances were compared to the results obtained by sensory panel analysis (table 1 below).

Table 1: Comparison between Euclidean Distances (E-Tongue) and Bitterness Scores (Sensory Panel)

Minor differences were observed (for D & H) and may be caused by a difference of dissolved additives. Moreover, a good correlation was obtained between Euclidean distances and the bitterness scores from the sensory panel for all products including the original product (R² = 0.9 in a linear regression model).

By adopting an acceptable bitterness threshold at a value of 2 (this corresponds to an euclidean distance = 600 calculated with correlation model), A, E, and F are considered as having an unacceptable bad taste. Therefore, Euclidean distances calculated based on the e-tongue data may be useful for the taste evaluation of generic FODT.

Conclusion

Using the e-Tongue it was possible to compare the overall tastes of all the medicines on a single graph. The instrument also allowed to discriminate products with a considerable bitterness, which is uncomfortable for patients.

Reference: [1] Famotidine Orally Disintegrating Tablets: Bitterness Comparison of Original and Generic Products, E. Tokuyama (a), C. Matsunaga (a), K. Yoshida (b), J.C. Mifsud (c), T. Irie (d), M. Yoshida (a), T. Uchida (a) - (a) Mukogawa Women’s University - (b) Primeitech – (c) Alpha MOS – (d) Kumamoto University - Chem. Pharm. Bull. 57(4) 382—387 (2009)