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Review

Usefulness and limitations of taste sensors in the evaluation of palatability and taste-masking in oral dosage forms

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ABSTRACT

The purpose of this review is to discuss the advantages and limitations of taste sensors in the evaluation of the taste of palatability of different oral dosage forms. First, we consider some ways in which the palatability of various pharmaceutical formulations including orally disintegrating tablets (ODTs) are tested using two different taste sensors. Second, we focus on the evaluation of palatability of ODTs. We compare the usefulness of three pieces of apparatus for estimating the disintegration time of ODTs. Finally, we compare the characteristics of the two taste sensors in the evaluation of palatability of various kinds of drug formulations.

1. Introduction

Of the various types of formulation on the pharmaceutical market, solid oral forms (e.g. tablets, capsules) are the most common. These formulations have many advantages, such as dose accuracy and relatively high stability, and also offer possibilities for modifying the drug release profile in order to delay or sustain a therapeutic effect. Their palatability, however, especially if they have a bitter taste, is also important in maintaining patient adherence and thereby allowing effective pharmacotherapy to be attained [1,2].

Even plain tablets may be associated with problems such as difficulty in swallowing, not only in pediatric or geriatric populations but also for handicapped or bedridden patients. This may be due to large tablets sticking to the throat mucosa, causing irritation of the pharyngeal region, coughing or choking. One way to eliminate such problems is the use of the orally disintegrating tablet (ODT) [3–7]. The most important advantages of the ODT are quick disintegration after contact with

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saliva in the mouth, facilitating swallowing, and ease of delivery, with no need for water to wash down the drug, thus increasing patient adherence.

As leading formulation of ODT, Zydis® [8], or WOWTAB (without water tablet) were developed and commercialized. Nowadays, many ODTs are available [9–13], owing to various manufacturing technologies developed by many researchers [14–21]. The developers of pediatric medicines particularly focus on issues of palatability for compliance reason [22,23]. Minisized ODTs have now been developed [24,25] and their usefulness recently evaluated.

ODTs are not only of particular benefit to patients with poor swallowing ability, but also to populations with busy lives, as they can be taken at any time and in any place. In some cases, however, palatability issues such as the bitterness or astringency of the active ingredient may decrease adherence, since the acute drug concentration reached in the oral cavity can be extremely high due to the immediate disintegration of the tablet in saliva. Therefore, taste-masking technology must be involved in the design of ODT formulations if the active ingredient is very bitter or astringent. The oral disintegration time of an ODT is a critical factor determining its palatability, rapid disintegration in the oral cavity being an essential feature of ODTs.

The quantitative evaluation of palatability is now an important component in the process of formulation development for various types of oral formulation, including liquids. Human sensation test is a major method to evaluate palatability of oral formulations [26–30]. However, the use of human volunteers for taste-testing requires the volunteers to be accurate and precise, while ethical issues may prevent human taste-testing of some active drugs, e.g. anti-neoplastics. The use of an artificial taste sensor removes these difficulties. We have used the taste sensor to evaluate the bitterness of many kinds of medicines (both basic and acidic drugs) and have demonstrated its ability to predict accurately the bitterness intensity experienced by human senses [31–52]. The sensor is now available worldwide.

2. Evaluation of taste including bitterness or astringency of medicines

2.1. *Insent taste-sensing system*

The first taste sensor, composed of lipid/polymer membrane was developed by Toko [53], and is now marketed as the Insent taste-sensing system (Intelligent Sensor Technology Inc., Atsugi, Japan) [54–56] (Fig. 1). The taste sensor output exhibits different patterns for chemical substances that have different taste qualities, i.e. bitterness, sourness, saltiness, umami and sweetness. We have previously evaluated the bitterness of various medicines and amino acids using this system and suggested that the sensor may be useful to predict quantitatively the bitterness of medicines [31–33]. Antibiotics including clarithromycin dry syrup, have been evaluated using this system, and a good correlation was obtained between the results of human gustatory sensation testing and the predicted bitterness intensity calculated from the taste sensor output [34]. Aminoleban EN, an elemental diet containing a large quantity of branched chain amino acids (BCAAs) which have a bitter taste, was also successfully evaluated using this system [35,36]. Kataoka et al. [39,40] evaluated bottled nutritive drinks using this system and found that the bitterness or sourness predicted by taste sensor output correlated well with the results obtained from human sensation testing. Not only the taste of medicines but also the suppression of unpleasant taste could be predicted by this system. Tsuji et al. [41] and Ishizaka et al. [42] reported on the

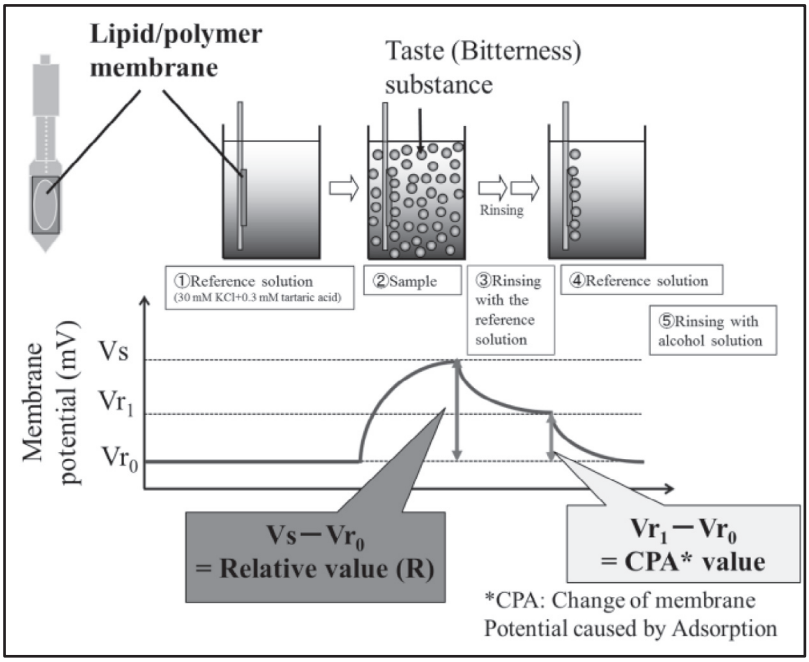

Fig. 1 – Measurement procedure of Insent taste-sensing system.