

# An Advanced Electronic Taste-sensor Technique for the Bitterness of Orally Disintegrating Film: Evaluation of Pullulan Films Loaded with Donepezil Hydrochloride

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Orally disintegrating films (ODFs) have been developed for helping the geriatric and pediatric patient, such as those who cannot swallow some medicines easily. ODFs can be taken without water or chewing. Prediction and suppression for bitterness of ODFs must be evaluated, because they disintegrate in the oral cavity and their bitterness sometimes is locally greater than the conventional tablets. The aim of this study is to demonstrate the feasibility of an advanced electronic taste-sensor system for evaluating the bitterness of ODFs.

**METHODS:** An orally disintegrating film was designed, loaded with donepezil hydrochloride (DH). Pullulan (Tokyo Chemical Industry, Tokyo, Japan) were used as film formers. Films were prepared using the solution/solvent casting method with the YBA-type Baker Applicator (Yoshimitsu Seiki, Japan), to make them thin and uniform. Disintegrating time and tensile strength were also determined. The taste analyses were performed by the Taste-Sensing System SA 402B (Intelligent Sensor Technology, Atsugi, Japan), using a BT0 sensor with a negatively charged membrane.

**RESULTS:** On the basis of taste sensor output profiles, the bitterness of films in various formulations could be verified. Following a period with no change about 20 seconds (the lag-time), the changes of sensor output begin to rise markedly. Increasing the amount of DH loaded in a film induce increasing of the sensor output. The length of lag-time is dependent on the types of film formers, the thickness of films and the types and amount of additives in the film formulations. The detection of ODF bitterness in the oral cavity is correlated strongly with release profiles.

**CONCLUSION:** This advanced technique could be used for evaluating the bitterness of ODFs with time course, especially at the initial stage of administration. The difference of taste-sensor output of pullulan ODFs loaded with DH could be detected.