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Improved palatability of gummi drug of epinastine hydrochloride using organoleptic taste-masking methods

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Gummi drugs are dried jelly formulations prepared by the addition of a gelling agent to saccharides, which are then cooled and solidified. Epinastine hydrochloride (Epi), which is commonly used as an allergy medicine for conditions such as allergic rhinitis, is used as a medicinal drug and an over-the-counter drug (OTC) for self-medication in Japan. The very bitter taste of Epi may affect its acceptability among patients. In this study, we aimed to improve the palatability of gummi drug containing Epi by using organoleptic masking (sweetener and flavor). Epi gummi formulations (Epi-G, 10 mg of Epi/3.5 g of gummi drug), and two other types of Epi-G were prepared by organoleptic masking with aspartame, cocoa powder, and chocolate flavoring (C-Epi-G); and a formulation with aspartame, L-menthol, and lemon flavor (L-Epi-G). A gustatory sensation test was performed on six healthy adult volunteers (age, 23.3 ± 1.8 years). We used a visual analog scale (VAS) to evaluate bitterness, sweetness, and the overall palatability of each Epi-G during chewing and immediately after spitting out the drugs. This study was approved by Ethics Committee of the Hamamatsu University School of Medicine. We developed three types of gummi formulations containing Epi: Epi-G, C-Epi-G, and L-Epi-G. In the gustatory sensation test, the VAS scores for overall palatability while chewing for C-Epi-G and L-Epi-G, with organoleptic masking, were 130% and 100%, respectively, of the value for Epi-G without masking. The score after spitting out for C-Epi-G was 130% that of the value for Epi-G. The use of gummi drugs of medicinal drugs to treat infant and geriatric patients allows them to swallow the drugs more easily while chewing, and improves palatability compared with other oral formulations. Therefore, gummi drugs may improve patient adherence to medication. We believe that gummi drugs represent an attractive formulation for both medicinal drugs and OTC.

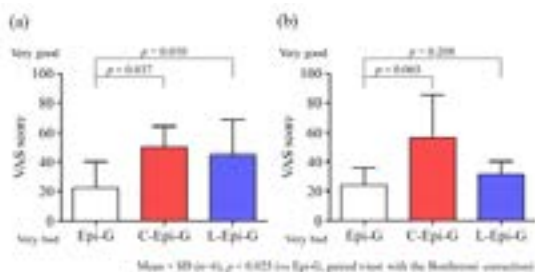


Fig. 1 VAS evaluation of overall palatability of each gummi drug during chewing (a) and after spitting out (b).

Recent Publications

1. Nakagaki F, Uchida S, Tanaka S, Namiki N. (2018) Palatability and Preference of Gummi Formulations with Various Pharmaceutical Characteristics. *Chem Pharm Bull.* 66:452-457.
2. Katayama T, Uchida S, Kamiya C, Tanaka S, Kashiwagura Y, Hakamata A, Odagiri K, Inui N, Watanabe H, Namiki N. (2018) Palatability and Preference of Gummi Formulations with Various Pharmaceutical Characteristics. *Chem Pharm Bull.* 66:452-457.

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3. Uchida S, Hiraoka S, Namiki N. (2015) Development of gummi drugs of aripiprazole as hospital formulations. *Chem Pharm Bull.* 63:354-60.
4. Sotoyama M, Uchida S, Tanaka S, Hakamata A, Odagiri K, Inui N, Watanabe H, Namiki N. (2017) Citric Acid Suppresses the Bitter Taste of Olopatadine Hydrochloride Orally Disintegrating Tablets. *Biol Pharm Bull.* 40:451-457.
5. Namiki N, Takagi N, Yuasa H, Kanaya Y (1998) Studies on development of dosage forms for pediatric use (V) oral mucosal irritation study of gummi drugs in hamster cheek pouch. *Biol Pharm Bull.* 21:87-89.

Biography

Shimako Tanaka is assistant professor at school of pharmaceutical sciences, University of Shizuoka in Japan. Her major interests include clinical pharmaceutical science, clinical pharmacology and pharmacokinetics. To provide an optimum drug dosage forms and personalized pharmaceutical therapy to enhance their benefits for patients, she is developing confectionary shaped dosage forms, orally disintegrating tablets and gummi drugs, and subjecting them clinical evaluations.

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