

## Development of Novel Orally Disintegrating Tablet by Applying a Low Hydrophobic Lubricant

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**Purpose.** Orally disintegrating tablets are becoming popular as one of the user friendly dosage forms. Many products have already been commercialized on the market by several pharmaceutical companies. However, most of these products require relatively complicated manufacturing processes and/or specialized machine in the production. Our purpose was to develop an original composition of orally disintegrating tablet by using conventional tablet manufacturing processes. **Methods.** The ingredients (sugar alcohol, disintegrant, low hydrophobic lubricant) were mixed, granulated with a small amount of water and dried at 60 °C for 3-4 hours. The dried granules were sized with a sieve of 600  $\mu$ m openings. Then, the sized granules were molded to a hardness value of 30~40 N. Time until the tablet is completely disintegrated with saliva was measured in the oral cavity of several healthy adult volunteers. Penetration rate of ethanol into a lubricant, defined by penetration velocity  $W^2/t$  of ethanol into a lubricant, was determined by a Processor Tensiometer (K-121, KRUSS GmbH). **Results.** Tablets containing three components were prepared by a wet granulation process. Typically, erythritol/mannitol were selected as the sugar alcohol. When HPS, L-HPC or Microcrystalline cellulose was selected as a disintegrant, fast disintegration was obtained in the oral cavity. The effect of low hydrophobic lubricants was compared, and L-Leucine, Talc, SSF and Stearyl acids provided faster disintegration, less than 30 seconds, in the oral cavity. When Sucrose Esters of Fatty Acids, Mg-St or Ca-St was selected, the disintegration time was prolonged. A good correlation between the disintegration time of tablets and penetration velocity of ethanol into the lubricants was observed. **Conclusions.** A novel orally disintegrating tablet technology was developed with a conventional manufacturing processes. The formulations containing a lubricant which had penetration velocity larger than 5  $\times 10^{-3} \text{ g}^2/\text{sec}$  provided fast disintegration time of 30 seconds or less. It was found that the penetration velocity of ethanol is a simple and valuable index to identify the proper lubricants contributing to rapid disintegration of tablets.