

Factors influencing on Palatability of Generic Products

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Even though generic medicines in Japan are approved by the Authorities with deep scientific data in related to chemical specification of bulk chemicals, stability, and bio-equivalency and so on, compared to the branded products, the information or data of the palatability of generic drug is unnecessary for the approval. In this presentation, I would like to focus on the quality of product such as the palatability or etc., with oral generic formulations, which might reduce the compliance of the generic product.

Firstly our research group evaluated the pharmaceutical quality and palatability of 12 CAM dry syrup formulations including the generic and branded products. In the evaluation of palatability for some generic products, intensity of the bitterness was increased over time for gustatory sensation test. In the original product, the content was almost 100% in every particle size group, but in several of the generic products, the content of some groups was uneven. Secondly, in the quantitative evaluation of palatability of famotidine-loaded orally disintegrating tablets (generic), the principal component analysis using taste sensor measurement without gustatory sensation test was very successful.

Overall the tight collaboration by sharing each knowledge among company, medicinal and academia people might be the most suitable method for development of the high quality guaranteed generic product and the achievement of the appropriate usage of generic medicine in the clinical site.

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