Value-added Type Generic Medicines (Oral Solid Formulations)

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Generic medicines (GE) can be marketed after the monopolistic sales period (re-examination period to examine the efficacy / safety and patent protection period) of branded originator medicines (BR). GE contain the same active pharmaceutical ingredient and are same in indication, efficacy, usage and dosage to BR with low-price. GE are developed based on the efficacy and safety data confirmed through long-term clinical use of BR, and are approved by demonstrating they are equivalent in efficacy and safety to BR with at least same quality. Value-added type GE (VA-GE) are developed based on the consideration to provide the additional value profitable for medical personnel, and ultimately for patient, such as easiness of administration, improved stability and prevention of malpractice by the improvement of formulation, container or package without influencing efficacy and safety. Here, the development cases of orally disintegrating (OD) tablet and dry syrup are presented as examples of VA-GE of oral solid formulations, and the topics such as fine particle coating, evaluation of taste and sensitive bitter-taste masking are introduced as key basic technologies to carry out pharmaceutical designs. As VA-GE can be marketed after many years from marketing of BR, they are results of knowledge from harmonizing the experience of the originators and the know-how of the GE makers, and are being developed having features needed in a medical scene, in addition to low-price. It is expected that in near future VA-GE will be understood correctly by medical personnel and patient, and superior products will be developed.