

APPLICATIONS OF X-RAY POWER DIFFRACTION IN PHARMACEUTICAL ANALYSIS

Tomikatsu KUBO¹, Akira KISHI²

¹Application Laboratory, Rigaku Corporation, 14-8 Akaoji-cho, Takatsuki-shi, Osaka
569-1146, Japan

²Product Planning and Marketing, Rigaku Corporation, 3-9-12 Matsubara-cho Akishima-shi,
Tokyo 196-8666, Japan

Tomikatsu_Kubo.pdf

Quality control is very important for pharmaceutical products since long ago. Especially check and control of polymorphism is very important for polymorphous organic materials under the guidance of U.S. Food and Drug Administration in the last a few years. But the check and control of polymorphism is very difficult, because polymorphous organic materials are often unstable. Mostly and easily organic materials metamorphose into another crystal phases by the effects of temperature, humidity and so on. Therefore it is very important to study the phase transitions such as hydration and dehydration. Most commonly X-ray powder diffraction (XRPD) and thermal analysis (ex. differential scanning calorimeter, DSC) are used to elucidate the structure of the active organic compound. The measurements of these analyses are often independent of each other. Temperature controlled XRPD techniques have been used for studying dehydration and phase transition of organic and inorganic substances in air and dry gas atmosphere. But Simultaneous XRD and DSC can overcome problems arising from separate measurements of XRD and DSC such as specimen inhomogeneity, the difference of the temperature measurement, the effect of specimen mass and self-generated atmosphere on the reaction. Therefore we can get good information of polymorphism about polymorphous organic materials by using simultaneous XRD and DSC system.

We would like to introduce simultaneous XRD and DSC system and some applications measurements of polymorphous organic materials such as pharmaceuticals. If we can prepare, we will introduce other application measurements (ex. Identification, Quantitative analysis and so on.)