제약공정 PAT(Process Analytical Technology) 소개
및 정제 코팅공정에서의 적용사례

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Since the US FDA's issuance of their final report 'Pharmaceutical CGMPs for the 21st Century' and their formal guidance document 'PAT: A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance', there has been a strong stimulation for the research activities in pharmaceutical industry and academia related with in-line or on-line measurements of critical quality attributes (CQAs) during manufacturing processes. As an introduction, current situations of domestic and global pharmaceutical industries as well as fundamental concepts of PAT will be explained.

The coating process has been operated as one of the key pharmaceutical processes for tablet manufacture and the precise control of film thickness should be extremely important in terms of stability, drug delivery characteristics, economy, and so forth. Recent experimental data (NIR-based in-line monitoring of film thickness during the coating process) will be presented with our novel approach combined. Finally, conclusions and subjects for future work will be given for in-depth discussion toward the PAT system implementation for pharmaceutical processes.