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Regulatory Prospective on Quality Evaluation of Pharmaceuticals

Hee-Sung Kim

Drug Evaluation Department, Korea Food and Drug Administration

Quality evaluation is essential to ensure the same quality and effectiveness of drug products. To assure the adequate quality of drugs, the government agency in charge, Korean Food and Drug Administration should establish and clarify the related regulation.

The KFDA's recommendations on quality evaluation of drugs are finally documented in the 2003 "Provision for Specifications and Test Procedures of Drugs". Also, the agency has recently adopted the guidelines for specification of dissolution testing, assay validation and residual solvent etc.

Presently, the revision of "Provision for Specifications and Test Procedures of Drugs" is progressed and the fundamental principle of revision is international harmonization and advance of a field of drug quality.

This presentation will provide an insight into the current regulatory issues and prospective on quality evaluation of pharmaceuticals based on proposed revision of the regulation.