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Quality by design approach for tablet formulations and flexible regulatory approach

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Abstract

Pharmaceutical product development knowledge is intensive, the product development process is quite complex. Recently, the drug industry has experienced major developments including nanotechnology, in production information, quality management systems and risk management and has developed modern production tools that can assist in ensuring the production quality.

Quality by Design (QbD) studies are applied in the pharmaceutical industry since 2004. The first step of its implementation started with the Process Analytical Technologies guideline, which was followed by the Q8, Q9, Q10 and Q11 guidelines.

During the multi-parameter processes of pharmaceutical production, it is necessary to make different variations in either the formulation or the process. However, these variations cannot be performed without permission from the pharmaceutical regulatory authorities. Design space (DS) is a production space provided by the control of critical parameters that are determined by the formulation and manufacturing process. In addition, working within this DS is not considered a change.

To evaluate the QbD principles, Ramipril was used as a model drug and direct compression tablets were designed with the application of INForm v.4 ANN. The results of the tablets containing respectively MgSt and SSF were evaluated by the program. With reference to the data obtained, all required measurements and evaluations were performed and the critical quality attributes were determined upon risk control.

And to demonstrate the flexibility of post-approval changes on ramipril tablets, which contain components from three different active pharmaceutical ingredient manufacturers, within the scope of the DS.

Biography

Buket Aksu has completed his Ph.D at the Ege University (Turkey) & Bradford University (UK) and postdoctoral studies from Istanbul University School of Pharmacy. She has also completed her Post Graduate degree on Management and Organization Department in the field of Social Sciences. She is the Corporate Relations Director of Santa Farma Pharmaceuticals. She has given 49 scientific, 32 social conferences and she has 8 scientific publications and 39 posters at national and international levels. She has attended more than 90 national and 45 international meetings.