

Chemometric modelling to predict concentration of API in a solution flow

Samd Guizani, Anamaria Angheluta, Josselin Saunier, Roennback, Robert

Ferring Pharmaceuticals

Chemin de la Vergognausaz 50, 1162 - Saint-Prex – Switzerland

samd.guizani@ferring.com

API concentration is obviously a critical Quality Attribute (cQA) of any Drug Product. In this work, a continuous process to manufacture aqueous solutions has been developed. And, the target is to develop a fast, precise and accurate method to determine the API content in the outgoing flow. A chemometric model has been applied to UV/Vis spectroscopic data in order to predict online the API concentration. This information would then be used to serve multiple purposes: real-time release of the solution, feedback to the manufacturing process in order to adjust critical Process Parameters (cPP) and, if necessary, divert non-conforming portions of the product.