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Analytical Test Method Validation (AMV) of Finished Pharmaceutical Products (FPP) & system suitability requirements

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The Objective of Validation of an Analytical procedure is to demonstrate that it is suitable for its intended purpose. It is applicable to identification, Control of Impurities and Assay. Analytical Test Method Validation for Dissolution Method follows almost the same procedure but only differs in the Acceptance criteria.

Analytical Test Method Validation Scheme discusses requirements to be done after Analytical test Method Development. The discussion will only cover Analytical Test Method Validation of Analytical procedures for the Assay of the active pharmaceutical ingredient (API), content of impurities and Acceptance criteria According to ICH Q2B, USP/FDA Guidance for Industry document for analytical test method validation, EP/BP, JP&WHO.

It will mainly cover HPLC Method Validation and its System Suitability Criteria.

This discussion is required for registration in, or export to the mentioned countries that follow such Guidance(s) as part of the CTD Quality module.

The Discussion will also cover the difference between Analytical Method Validation and Analytical method verification for Compendial Procedures.

Biography

Rober Remon Saad Habashy has completed his Bachelor degree in pharmaceutical science 2007 at the age of 22 from Misr International University School of Pharmacy. He completed his Total Quality Management (TQM) Diploma from the American University in Cairo 2009. He became certified Six Sigma Black Belt (CSSBB) from the American Society for Quality (ASQ) October 2011 as well as Diploma in Quality Assurance in the same year from the American supplier institute (ASI). He is the Training Chair at the American Society for Quality Local Member Community (LMC) in Egypt. He is a core member senior Research & Development pharmacist at Amoun Pharmaceutical Company Cairo Egypt. He works at the R&D Department and responsible for Analytical test method development and Validation as well as formulation and pre-formulation studies, Product / process design for human/vet Pharmaceutical product.

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