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Stability indicating by HPLC Method Development and Validation

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High performance liquid chromatography (HPLC) is an integral analytical tool in assessing drug product stability. HPLC methods should be able to separate, detect, and quantify the various drug-related degradants that can form on storage or manufacturing, plus detect and quantify any drug-related impurities that may be introduced during synthesis. Forced degradation studies of new chemical entities and drug products are essential to help develop and demonstrate the specificity of such stability indicating methods. In addition to demonstrating specificity, forced degradation studies can be used to determine the degradation pathways and degradation products that could form during storage, and facilitate during formulation, development, manufacturing and packaging. For marketing applications, current FDA and ICH guidance recommends inclusion of the results, including chromatograms of stressed samples, demonstration of the stability-indicating nature of the analytical procedures, and the degradation pathways of the API in solid state, solution, and drug product. A review of literature reveals that a large number of methods reported over the period of last 3 – 4 decades under the nomenclature 'stability-indicating', but most of the reported methods fall short in meeting the current regulatory requirements. Hence a systematic approach for the development of validated SIAMs that should meet the current ICH and regulatory requirements. The following will provide some suggestions for performing forced degradation studies based upon available guidance from the ICH and FDA.

Biography

Muhammad Amir Ilyas has 15 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, Product development and Pharmaceutical manufacturing, Process Planning, Method development, Method validation, Statistical Methodology, Process & Cleaning Validation, and Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, CTD Documents, ISO 9001:2008, 13485-2003, 14001-2004 and 17025:2017 have strong scientific, analytical, statistical, managerial and training skills.

Currently he is working as a Senior Manager Research and Development for Novamed Pharmaceuticals. It is toll manufacturing oriented company, manufacturing of companies like Getz Pharma, ICI, SEARLE, Macter, Ray, and for Sanofi-Aventis. He is also looking after the Product Development of Novamed Healthcare, the nutraceutical and cosmeceutical manufacturing plant

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