Analytical Quality by Design: an emerging tool for Regulatory Flexibility in Chromatography

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Abstract

It is a well-known fact that chromatography is method of separation of mixture of drug substance through instruments like HPLC, UHPLC, UPLC and hyphenated techniques such as LC-MS, LC-NMR, etc. The major intent of chromatography is to find out the occurrence or measurement of the relative proportions of analytes in a mixture. But the modern scientific technology equipped with implementation of Quality by Design (QbD) is a systematic approach for robust product development with less span of time as per regulatory compliance and ICH recommended quality guidelines. This QbD enabled holistic approach especially to the analytical development is well-known as Analytical Quality by design (AQbD), which is recognized as a rational and rapid analytical methodology, that can minimize more solvent consumption, reagents, additional resources during chromatographic analysis. In this current review, an attempt has been made to elucidate the applications of Design of Experiment (DoE) to the chromatographic development through its modern statistical software's which enhances for regulatory flexibility and homogenous product development.

Biography:

Mr. (Dr.) Bikash Ranjan Jena has over 8.5 years of academic and research experience in the field of Pharmaceutical Analysis, especially systematic development and validation of some selected anticancer molecules employing Analytical Quality by Design (AQbD) approach and Design of Experiments (DoE). Currently, he is perusing his Ph.D. at KL Deemed University, (UGC, NAAC A ++ accredited, Category 1, University) Vaddeswaram, Guntur, A.P., India and working at SoPLS, Centurion University of Technology and Management (CUTM), Jatni , Bhubaneswar, Odisha, India. Till date, he has authored over 30 publications (research & review, short communications, editorials review) in various high impact peer-reviewed journals, 8 book chapters in reputed Publisher like Springer, Elsevier etc., to his credit. He has more than 1yr of industrial experience in Regulatory affairs and more than 6 months of industrial experience in Analytical R & D during his Masters in Pharmaceutical Analysis (M. Pharm). He is also serving as an Advisory Board Member of the journal WJPR, Board Member in 2 international Journal and Reviewer of more than 8 international Peer reviewed impact Journals. he has earned published and cited record (Google Scholar citations 37, Scopus Publications 10, H-Index: 4, Research Gate Score: 10.67). Mr. (Dr) Jena has also participated and presented his research work at various national and international conferences like IPC and life Members of professional bodies like Institute of Scholars (InSc) and APTI, India. He has received recently the "Young Scientist Award-2021" from VD GOOD Professional Association during International Scientist Awards for engineering, Science and Medicine and "Young Achiever Award-2021" from Institute of Scholars (InSc) for outstanding contribution of Research article published in the field of Pharmaceutical sciences.

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