Mr. Suhas Yewale

Associate Director, Techno Commercial Sotax India Pvt. Ltd

Title: Dissolution Testing of Novel Drug Delivery System

Abstract : As novel formulations have become more prevalent due to complexities of drug delivery, there has been an increased development of modified testing methods to characterize the *in-vitro* release of these dosage forms. Nanoparticulate systems have emerged as prevalent drug delivery systems over the past few decades. These delivery systems (such as liposomes, emulsions, nanocrystals, and polymeric nanocarriers) have been extensively used to improve bioavailability, prolong pharmacological effects, achieve targeted drug delivery, as well as reduce side effects.

This presentation provides an overview of the current in vitro dissolution/release testing methods such as dialysis, sample and separate, as well as continuous flow methods. As per USP general chapter <1088> “No product, including suspensions and chewable tablets, should be developed without dissolution or drug release characterization where a solid phase exists.” And “Dissolution/ drug release testing is required for all solid oral Pharmacopoeial dosage forms in which absorption of the drug is necessary for the product to exert the desired therapeutic effect”

In the pharmaceutical industry, dissolution testing is an important tool in both **Drug Development** and **Quality Control**. Ideally, an in-vitro release method should be **discriminatory** and be able to simulate **in-vivo** conditions, **release mechanisms** and enable the establishment of an **IVIVC**. An in vitro release rate reflects the combined effect of several **physical and chemical properties** in both the drug substance and the drug product.

Although there is no compendial in-vitro drug release method available for such complex new drug delivery formulations, FDA has recommended USP Type 4 apparatus for the drug release testing.

USP Type 4 apparatus with its open loop and close loop configuration has various cells designs suitable for the development of discriminating in-vitro drug release testing methods for the non-conventional dosage forms such as medical devices, injectable suspensions, suppositories, soft-gelatine capsules, creams, gels, ointments, microspheres and APIs etc.

Mr. Suhas Yewale
Professional Biography

Mr. Suhas Yewale did M.Sc. in Analytical Chemistry from Mumbai University. He is a meticulous and a versatile pharma professional, holding rich experience of 28 years in Analytical Research and Development for Generic Pharma industry. He is also an approved Chemist in “Chemical & Instruments” Maharashtra State FDA., Lead Auditor Medical Devices Quality Management System (ISO 13485) from BSI and Trustee Member of “Society for Pharmaceutical Dissolution Science (SPDS)”. He has excellent skills in Analytical Method Development, Method Validation, Analytical Tech-transfer and Stability studies for more than 70 ANDA’s and EU Dossiers. His experience includes successful completion of regulatory audits by US FDA, UK MHRA and EU Agencies.

Mr. Yewale has worked with leading national and multinational generic Pharma companies like – Sandoz Private Ltd.; Glenmark Pharma, Famy Care (now Mylan), Unosource Pharma Ltd. and Par Formulations Pvt. Ltd. at Senior Management Level. Currently, he is an “Independent Analytical Research and Development Consultant” in the Pharma Industry and is associated with the following organizations:

- SOTAX INDIA PVT LTD as “Associate Director Techno Commercial” (Leading Dissolution Application Lab in NFRT at BCP)
- National Facility For Research & Training (NFRT) as “Sr. Consultant Techno Commercial”
- ImageProvison Technology Pvt. Ltd. as “Pharmaceutical Analysis Consultant” for Particle Size Characterization by Microscope Image Analysis Technique.
- Raaj GPRAC [‘Raaj Global Pharma Regulatory Affairs Consultants]Training Institute as a “Visiting Faculty Trainer” on ICH Quality topics - ICH Q1(R2), ICH Q2, ICH Q3, ICH Q6