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Gujarat FDCA deploys USP's Dissolution Testing to address drug quality and efficacy concerns

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USP in discussion to upskill manpower of pharma companies

The United States Pharmacopoeia (USP) has collaborated with the Gujarat Food and Drug Control Administration (FDCA) to address the knowledge gap on Dissolution testing amongst the drug manufacturers.

The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. Dissolution and drug release are terms used interchangeably.

According to the Gujarat FDCA Commissioner Dr Hemant G Koshia, “Gujarat state drug inspectors recently got hands-on training on the role of dissolution testing in quality and efficacy of the medicinal product for the first time in collaboration with the Gujarat FDCA. The training and partnership with the USP comes at a time when the Gujarat FDCA has detected major quality issues arising due to dissolution testing failures over the past one year.”

Dr Koshia further added that we can overcome quality and efficacy issues by getting equipped with training programmes of USP. Each medicine has its own delivery system and Dissolution, or in vitro release, is linked to the release of the drug into the body, making it available for absorption, and finally the clinical outcome.

Regulatory experts have informed that USP dissolution tests are legal requirements as it is today specified in all major pharmacopoeias.

Dissolution testing measures the extent and rate of solution formation from a dosage form, such as tablet, capsule, ointment, etc. To properly evaluate the dissolution of drug products, it is critical for procedures to be standardised. This standardisation helps to show consistent quality in production and may serve as a predictive measure of efficacy. A dissolution test uses an apparatus with specific test conditions in combination with acceptance criteria to evaluate the performance of the medicinal product.

USP is also in discussion to upskill manpower of pharma companies and MSMEs in labs and offer them courses at a reduced rate or free of cost to help them adopt quality practices.

The standards in the USP and the National Formulary (NF) are used to help ensure the quality of medicines and their ingredients, and to protect the safety of patients.

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