Charles Ischi AG
TESTING TECHNOLOGY

Press Release
15.01.2020

Revision of USP<1217> Tablet Breaking Force

The Revision

The United States Pharmacopeia (USP) General Chapters - Dosage Forms Expert Committee recently revised the USP <1217> standard to recognize the need for routine testing of tablet breaking force during formulation and manufacture. The new test ensures a constant level of high quality results during tablet production. The revision enhances information available on apparatus description, including designs in which constant loading rate or constant platen movement is employed, typical ranges of movement or loading rate, sensitivity for breaking force, methods of calibration and sample size.

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Charles Ischi AG – Testing Technology is offering fully compliant testing equipment meeting with the revised United States Pharmacopoeia USP-1217 tablet breaking force standards with its automatic QC and IPC tablet testing system UTS4.1 and its licensed operation Software.

This means that tablets developed and produced using the combined system will conform to all latest pharmaceutical industry regulations.

Hardness redefined

The latest revisions now apply to chewable and lozenge formats and reconsider the dissolution, disintegration, friability, and other tests that must be applied to assess strength of the compacted form and its interactions with water and other liquids. It recognizes that Tablet Breaking Force (or 'crushing force'), rather than the misleading term 'hardness', is the key criterion that must guide tablet development and serve as the key quality specification.

The revised specification is also widened to include chipping and abrasion as having impact on manufactured quality, especially in respect of coating and packaging.

Tablet orientation

Significantly, the determination of tablet breaking force is revised to specify that when using mechanical drives to assess 'crushing force', platen faces should not only be smooth polished and precision ground perpendicular to direction of movement, but should also be perpendicular to tablet supporting surface to ensure uniform contact with tablet sides from top to bottom.

The tests must be carried out at constant speed or constant force increase and with consistent orientation in the tester to ensure true comparability of results.

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Compliant QC and IPC tablet testing

Charles Ischi IPC and UTS testing systems ensure compliance with the latest standards with revisions to the software specifications to substitute Tablet Breaking Force for Hardness.

Testers ensure sophisticated and reliable tablet orientation with the patented Oblong Centering Device (OZB) available as an optional module that can be retro-fitted to all version 4.0 and later UTS testing systems. The centering device is installed above the hardness measuring station to ensure elongated products, such as oblong tablets, are precisely positioned and guided without contact during the hardness test. Customized centering jaws can be provided for unusual shaped tablets.

Ph21 Software revisions

Ph21 Software has also been revised to make measurement of tensile strength available as option and adds new OSD types and forms, such as: chewable tablets, lozenges, etc.

The Charles Ischi automatic IPC tablet testing system is compact, mobile, can be used off-line and in-line connected with all makes and models of tablet press machinery and can network tablet batch data to a central server for centralized data recording and IPC processing. The system can test for trends in weight, hardness, thickness, diameter/length and width variation in tablets, sending results to a central server, generating IPC data that can be translated to full production.

The use of industry standard Ph21 Software ensures full FDA 21CFR part11 GMP compliance, also allowing full archiving of all results and product recipes, with electronic batch reports.

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