

PVT and Dissolution Performance Verification Standard - Prednisone



We listened!

Dissolution Performance Verification Standard (DPVS) - Prednisone tablets have been developed to create greater reassurance in the performance qualification of Dissolution Apparatus 1 and Dissolution Apparatus 2. This will be the official standard for PVT when the proposed revision for *USP* General Chapter <711> *Dissolution* becomes official.

The Performance Verification Test, General Chapter <711>, is a holistic test that demonstrates the suitable operation of the entire dissolution test assembly. DPVS – Prednisone will help ensure comprehensive qualification of instruments using PVT, so you can be confident of the dissolution profiles of medicines evaluated using apparatus 1 and 2.

Features and benefits of DPVS - Prednisone

- Stable throughout its shelf-life, hence lower tablet-to-tablet variability
- Sensitive to critical changes in the setup of both apparatus 1 and 2
- Ball-shape of the tablet to ensure consistent positioning of the tablet in apparatus 1 and 2
- Less sensitive to media degassing, thus providing better sensitivity to other critical operational and setup parameters
- New easy-to-open blister packaging with push-through design and additional sachet packaging to protect against environmental moisture

These features improve accuracy and sensitivity, increasing your confidence in the dissolution system suitability. You can have peace of mind in your instrument set-up and the PVT test using the new DPVS - Prednisone.

Importance of PVT versus mechanical alone

Product recalls due to quality issues can be costly. They can harm patients, disrupt business operations, may trigger regulatory investigations and require costly remediation. They can also damage customer confidence and lead to reduced market share. Accurate dissolution results help ensure patient safety and avoids recalls. Therefore, ensuring that your dissolution apparatus is working properly is critical.

Mechanical qualification alone does not provide sufficient evidence that the apparatus is performing satisfactorily. Mechanical calibration focuses on individual, measurable operational parameters of the dissolution assembly. Performance Verification Testing (PVT) assesses the operation of the whole assembly, to verify that the different components are working together properly. Both mechanical and PVT are necessary to ensure that a dissolution instrument is fully qualified.

A failing PVT result may be an indication of a malfunctioning dissolution bath, a dissolution assembly that is not set up correctly, or analyst error, among other possible sources of failing dissolution results. The ranges for the geometric mean (GM) and the coefficient of variation (%CV) are an integral component of the PVT and are obtained from a multinational collaborative study for each new lot. Those two statistics, GM and %CV, help the laboratory using the reference standard determine if their results are accurate and reproducible within the context of ISO 5725-6 Accuracy of Measurement Methods and Results. Thus, the USP PVT reference standard provides a benchmark to compare dissolution test results to those obtained by competent dissolution scientists throughout the world.

Support

For support on DPVS - Prednisone, please contact:



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