

ASTM vs. USP TOOLKIT

The USP has suggested that physical and (MQ) mechanical attributes (such as height, centering, wobble, and speed) of the Dissolution Instrument be measured. Followed by a chemical calibration / verification using Prednisone Tablets (PVT).

The US Food and Drug Administration has decreed that a mechanical qualification (ASTM E2503-07) can be used to validate apparatus 1 and 2. Once a unit meets all of the mechanical specifications included in the MQ, it is considered calibrated.

	ASTM	COMMENT	USP TOOLKIT	COMMENT
SERIALIZATION OF PARTS	No specific measurement*	All parts are to be traceable to a COC or COA	No specific measurement*	All parts are to be returned to the position they were measured in
BASKET/PADDLE HEIGHT	±8% of required height or 25mm ±2mm	This would be ±2mm for a 25mm requirement	25mm ±2mm	
ROTATIONAL SPEED	Within 2% or ±2 RPM, whichever is greater		±1 RPM at set value	The rotation speed should be evaluated at both 50 rpm and 100 rpm
SHAFT WOBBLE	≤1mm total runout	Measurement at about 2cm above paddle	<1mm total wobble	Measurement at about 1cm above paddle
BASKET WOBBLE	≤1mm total runout	Measurement on bottom rim of basket	<1mm total wobble	Measurement on bottom rim of basket

*Distek recommends the use of serialized & certified parts to ensure complete compliance. Distek serialized & certified parts are issued with a Certificate of Compliance.

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	ASTM	COMMENT	USP TOOLKIT	COMMENT
VESSEL/SHAFT CENTERING	≤1.0mm from centerline	Measured at the top of the vessel and just above the paddle or basket	NMT (not more than) 2mm for 360° rotation	Measured not more than 2cm below rim of vessel
SHAFT VERTICALITY	NMT (not more than) .5° from 90°	Measured 2 points 90° apart on the length of the shaft	NMT (not more than) .5° from 90°	Measured 2 points 90° apart on the length of the shaft
VESSEL VERTICALITY	≤1° from vertical from two positions 90° apart	Measured at 2 points 90° apart on the wall of the vessel	NMT (not more than) .5° from 90°	Measured at 2 points 90° apart on the wall of the vessel
VESSEL PLATE LEVEL	No specific measurement		Inclination NMT (not more than) .5° in two orthogonal directions	Vessel plate surfaces in X and Y directions
SURFACE LEVEL	No specific measurement		Not more than 1° surface inclination	Bench surfaces in X and Y directions
VIBRATION	No significant vibration in the apparatus or medium		Should be limited by a high inertial mass of the bench top	
TEMPERATURE	±0.5°C of set point in each vessel		Highest and lowest vessel temps should be within 0.4°C of each other	This result is to be determined after vessel temp equilibration
PERFORMANCE VERIFICATION TEST (PVT) REQUIRED?	Not required		USP Prednisone Tablets RS	