



DISSOLUTION SYSTEMS MECHANICAL QUALIFICATION

Standard MQ Test Suite

This document describes the test program for qualifying Dissolution systems with apparatus 1, 2, 5, and 6; the following table lists all MQ tests.

Test	Setpoints and Parameters	Limits
Component Verification	NA	NA
Basket/Paddle Depth	Depth (Height): 25 mm	Accuracy $\leq$ 8% of setpoint ($\pm$ 2 mm)
Wobble	App 1 measured at basket shaft and basket rim; app 2 at paddle shaft; rotation speed of 50 RPM for all measurements	Measurements are $\pm$ 1.0 mm from the axis
Shaft Verticality	Measurement 1: point on vertical axis Measurement 2: 90° from measurement 1	Measurements are $\leq$ 0.5° from vertical*
Vessel Verticality	Measurement 1: Midway point on cylindrical part of vessel Measurement 2: 90° from measurement 1	Measurements are $\leq$ 1.0° from vertical*
Vessel Centering	Center position set; upper and lower points are measured	Measurements are $\leq$ 1.0 mm from centerline
Rotational Speed (RPM)	Speed 1: 50 RPM Speed 2: 100 RPM	Speeds are $\pm$ 2.0 RPM from setpoint
Vessel Temperature Accuracy	Temperature: 37°C	Accuracy $\leq$ 0.5°C
Vessel Temperature Stability	Temperature: 37°C	Stability $\leq$ 0.5°C

* Or within bubble if a mechanical (vs. digital) gauge is used

Test Design and Rationale

Component Verification

Description: This test captures the status of the verification certificates for components (vessels, shafts, baskets, and paddles, as applicable). Components should comply with the specifications listed in the USP General Chapter <711> Dissolution.

Basket/Paddle Depth

Description: This test verifies that the apparatus is set to the desired height (distance from basket/paddle to vessel bottom).

Procedure: The actual distance between the bottom of the vessel and bottom of the basket or paddle is determined. If the depth of the basket/paddle is adjustable, first a depth gauge is used to set the distance between the bottom of the paddle blade or basket and the bottom of the vessel. The depth gauge is set at 25 mm and placed on the bottom of the vessel. Each shaft is raised into the apparatus drive module. The drive unit is then lowered to its operating position. The paddle or basket is then lowered into the vessel until it touches the top of the depth gauge. The shafts are locked into this height. This is repeated for each shaft.

Wobble

Description: This test evaluates wobble, calculated as the absolute value of the difference between maximum and minimum readings.

Procedure (Shaft for App1/2): A runout gauge is placed on top of the vessel plate, and the drive module is positioned so that the gauge probe touches the shaft about 2 cm above the top of the paddle blade or basket. The gauge is placed so that the probe

slightly presses in on the turning shaft. If a mechanical gauge is used, the gauge's pointer should read slightly more than zero. The pointer will vary from a minimum to a maximum reading, and the difference is called the wobble.

Procedure (Basket for App 1): A runout gauge is placed on top of the vessel plate and the drive unit is positioned so that the gauge probe touches the bottom rim of the basket. The gauge is placed so that the probe slightly presses in on the turning shaft. If a mechanical gauge is used, the gauge's pointer should read slightly more than zero. The pointer will vary from a minimum to a maximum reading and the difference is called the wobble.

Shaft Verticality

Description: This test verifies shaft verticality in two directions, 90° apart on the vertical axis.

Procedure: Lower the drive unit to where it would be during an actual dissolution test. If necessary the shaft verticality may be checked with the shafts raised above the drive unit. Place an accurate bubble level on the front edge of each of the shafts. The bubble should be within the lines of the level. Rotate the level 90° so it is on the side of the shaft. The bubble should again be within the lines of the level for each shaft. If the shafts are not vertical adjust the feet of the apparatus until they are vertical. A digital leveling device may also be used to determine the shaft verticality. The shaft must be $\leq 0.5^\circ$ from vertical.

Vessel Verticality

Description: This test verifies vessel verticality with two measurements 90° apart at a midpoint on the cylindrical portion of the inside vessel wall.

Procedure: The vessel verticality can be calculated using the centering measurements and the difference in height between the two measurements or it can be determined using a digital leveling device placed on the inside wall of the vessel.

The verticality should be determined at two positions 90° apart. After each vessel has been centered and made vertical, each vessel and vessel plate opening must be numbered and a mark must be placed on the lip of each vessel and on the vessel plate directly next to the mark on the vessel lip. Each vessel must be returned to the same vessel plate opening and positioned in the exact same position inside the vessel plate opening for all future dissolution tests.

Vessel Centering

Description: This test verifies vessel centering.

Procedure: A mechanical or digital centering device that centers the inside of the vessel around the shaft or a surrogate shaft can be used. The centering is measured at two positions inside the vessel in the cylindrical portion, one near the top but below the rim and one just above the bottom portion of the vessel. The shaft or surrogate shaft must be centered within 1.0 mm from the center line.

Rotational Speed (RPM)

Description: This test verifies rotational speed of the shafts.

Procedure: A tachometer is used to measure the rotational speed of the paddle or basket. The shafts should be rotating smoothly at ± 2 rpm of the target value.

Vessel Temperature Accuracy

Description and Procedure: This test uses a calibrated thermometer to verify that the media temperature reaches the system setpoint.

Vessel Temperature Stability

Description: This test uses a calibrated thermometer to determine the stability of the vessel temperature.

Procedure: Stability is calculated as the delta between the highest and lowest measured temperatures.

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