

Qualification Test Specifications for Dissolution Test Systems

Test	Set Points/Range	Acceptance Criteria
Rotational Speed	Rotational Speed 1 = 50 rpm Rotational Speed 2 = 100 rpm	Speed \pm 4% rpm of the set speed
Runout (Wobble)	Baskets = the rim at 50 rpm Paddles = approximately 2mm above the paddle blade at 50 rpm	Wobble: \leq 1.0 mm
Shaft Verticality	Measurement 1 = X-axis Measurement 2 = Y-axis	$90^{\circ} \pm 0.5^{\circ}$ for both the x-axis and y-axis positions
Paddle/Basket Depth	Bottom of the basket or paddle blade to the bottom of the vessel	25 ± 2 mm
Vessel Centering	2 orthogonal positions	Centered in both directions
Vessel Support Plate Level	Measurement 1 = X-axis Measurement 2 = Y-axis	Level in the x and y-axis
Timer Accuracy	30 minutes	\pm 1%
Vessel Temperatures	37°C	\pm 0.5°C
Geometric Mean (GM)	6 or 12 dissolution samples	See current USP certificate for Prednisone
% Coefficient of Variation (%CV)	6 or 12 dissolution samples	See current USP certificate for Prednisone

Visit [TRANSCAT.com](https://www.transcat.com) >

sales@transcat.com | 800.828.1470

Overview for Above Mentioned Tests

1. Rotational Speed

DESCRIPTION:

The rotational speed of all stirring element shafts are measured using a calibrated QA Station. The rotation speed will be evaluated at both 50 rpm and 100 rpm.

SPEED CALCULATION:

Abs (Speed set point – Speed measured)

UNDERLYING PRINCIPLE:

Rotational speed accuracy is important to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

2. Runout (Wobble)

DESCRIPTION:

Using a calibrated QA Station, runout is measured for each stirring element at the rim of the basket for Apparatus 1 and near the bottom of the shaft, approximately 2mm above the paddle blade for Apparatus 2. Rpm set point is 50.

RUNOUT CALCULATION:

Abs (Runout set point – Runout measured)

UNDERLYING PRINCIPLE:

Runout (wobble) must be measured to ensure the stirring elements do not contribute to significant motion, agitation or vibration.

3. Shaft Verticality

DESCRIPTION:

Using a calibrated QA Station, measure the shaft verticality near the top of each shaft. Measurements are taken at two orthogonal positions. The first measurement is taken along the X-axis and the second measurement is taken along the Y-axis positions.

VERTICALLY CALCULATION:

Abs (Verticality set point – Verticality measured)

UNDERLYING PRINCIPLE:

Shaft verticality is important to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

4. Paddle/Basket Depth

DESCRIPTION:

Basket and paddle depth is measured between the bottom of the basket or paddle blade and bottom hemispherical portion of the vessel.

DEPTH CALCULATION:

Abs (Depth set point – Depth measured)

UNDERLYING PRINCIPLE:

Basket and paddle depth accuracy is important to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

5. Vessel Centering

DESCRIPTION:

Using a calibrated Steel Rule, vessel centering is measured at 2 orthogonal positions.

CENTERING CALCULATION:

Abs (Centering set point – Centering measured)

UNDERLYING PRINCIPLE:

Vessel centering accuracy is important to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

6. Vessel Support Plate Level

DESCRIPTION:

Using a calibrated QA Station, vessel support plate level is measured on the clear surface of the vessel support plate in two orthogonal directions, 90° from each other. One is measured along the X-axis and the other along the Y-axis.

LEVEL CALCULATION:

Abs (Level set point – Level measured)

UNDERLYING PRINCIPLE:

Vessel support plate must be level to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

7. Timer Accuracy

For Dissolution Systems that do not contain a timer, the section is Not Applicable.

DESCRIPTION:

Using a calibrated timer, simultaneously start the timer while initiating the rotation of the drive unit. After 30 minutes has elapsed on the drive unit display, record the elapsed reading from the timer.

ACCURACY CALCULATION:

Elapsed time (min) x 60 seconds/min

UNDERLYING PRINCIPLE:

The time of dissolution sample pulls are important to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

8. Temperature Accuracy

DESCRIPTION:

Using a calibrated thermometer, measure and record the initial and final temperatures of the dissolution medium in each vessel.

ACCURACY CALCULATION:

Abs (Temperature set point – Temperature measured)

UNDERLYING PRINCIPLE:

The temperature in each vessel must maintain an accurate temperature throughout the dissolution to obtain reproducible and valid dissolution testing results to assure a properly qualified dissolution test assembly.

9. Geometric Mean (GM)

DESCRIPTION:

Perform dissolution testing according to USP <711> and calculate the % dissolved for each vessel. Convert % dissolved to the natural log scale to determine the geometric mean (GM).

GM CALCULATION:

1st Stage of the Two Stage Test:

Run 1: x_1, x_2, \dots, x_n in natural log scale: $\ln x_1, \ln x_2, \dots, \ln x_n$

$GM = \exp(\text{average}(\ln x_1.. \ln x_n))$

Where: Exp = exponential (e^x)

2nd Stage of the Two Stage Test:

$GM = \exp(\text{average}((\text{average}(\ln x_1.. \ln x_n)), (\text{average}(\ln x_{n+1}.. \ln x_{2n}))))$
 $= \exp(\text{average}(\ln x_1.. \ln x_{2n}))$

UNDERLYING PRINCIPLE:

Prednisone tablet testing allows a laboratory to verify the operation of their dissolution system.

10. % Coefficient of Variation (%CV)

DESCRIPTION:

Perform dissolution testing according to USP <711> and calculate the % dissolved for each vessel. Convert % dissolved to the natural log scale to determine the % Coefficient of Variation (%CV).

% CV CALCULATION:

1st Stage of the Two Stage Test:

$$\%CV = 100 * \sqrt{\exp(\text{var}(\text{Ln } x_1 : \text{Ln } x_n)) - 1}$$

Where: Exp = exponential (e^x)
var = variance
sqrt = square root
* = multiply
100 = conversion factor to percentage

2nd Stage of the Two Stage:

$$\% CV = 100 * \sqrt{\exp(\text{average}(\text{var}(\text{Ln } x_1 : \text{Ln } x_n), \text{var}(\text{Ln } x_{n+1} : \text{Ln } x_{2n}))) - 1}$$

Where: Exp = exponential (e^x)
var = variance
sqrt = square root
* = multiply
100 = conversion factor to percentage

UNDERLYING PRINCIPLE:

Prednisone tablet testing allows a laboratory to verify the operation of their dissolution system.

Visit **TRANSCAT**.com >

sales@transcat.com | 800.828.1470

TRANSCAT[®]
Better by every measure

35 Vantage Point Drive 800.828.1470
Rochester, NY 14624 Transcat.com