

Dissolution Tester PQ Checklist

Company name: _____ Name: _____
 Company address: _____ Position: _____
 _____ Telephone: _____
 _____ Preferred date for services: _____

PQ Checklist – Items needed to complete USP Performance Verification Test (PVT)

Glassware

- 2 x 500 mL volumetric flasks
- Various sizes of volumetric flasks (for standard preparation)
- 1 x 500mL graduated cylinders
- 2 x 4-L vacuum flasks (sidearm) or equivalent for degassing
- 2 x 4 L flasks or beakers
- 1 x 20 L carboy for preparing bulk media
- Disposable test tubes 16x100mm (4 per vessel tested)
- Several small beakers

Equipment

- 1 x UV-VIS Spectrophotometer (calibrated), with cuvette (10mm)
- 1 x Analytical balance (calibrated) – for standard
- 1 x Analytical balance (calibrated) – for dissolution media
- 2 x Stir plates, 1 capable of heating
- 1 x Sonicator
- 1 x Vacuum pump with appropriate tubing for degassing media – or alternative validated method for deaeration

Miscellaneous

- 10 mL (or larger) luer lock syringes, 4 per vessel tested
- 2 x Pipette bulbs
- 2 x Test tube racks
- 0.45 micron filters (for degassing)
- Filters for sample filtering (4 per vessel tested)
- Several transfer pipettes
- Several stir bars (both small and large)
- Several spatulas

Reagents and Standards

- USP Prednisone tablets (current lot)
- USP Prednisone Reference Standard (current lot)
- Distilled or deionized or purified water source
- USP alcohol (95%, 190 proof)

I understand that if the installation site is not prepared in accordance with the enclosed instructions, additional installation charges may apply.

Signed: _____ Date: _____

