



U.S. Pharmacopeia
The Standard of Quality™

USP DISSOLUTION CALIBRATOR, DISINTEGRATING TYPE

USP Prednisone Tablets RS Lot O0C056 (10 mg nominal prednisone content per tablet)

This USP Dissolution Calibrator is provided for use in the *Apparatus Suitability Test* for USP Apparatus 1 and 2 in the USP General Test Chapters on DISSOLUTION <711> and DRUG RELEASE <724>. Do not expose the tablets to excessive humidity.

Dissolution Medium- Heat a suitable amount of water, while stirring gently, to about 41°. Filter under vacuum through a 0.45- μ m-porosity membrane into a suitable filtering flask equipped with a stirring device. Seal the flask and continue to apply vacuum while stirring for an additional five minutes. The temperature of the *Dissolution medium* does not fall below 37° prior to the initiation of the test.

Procedure- [See DISSOLUTION <711> and DRUG RELEASE <724> in the current USP.] Determine the quantity of prednisone, C₂₁H₂₆O₅, dissolved at thirty minutes, in each vessel, expressed as percent of the labeled amount. Use 500 mL of deaerated water as the *Dissolution medium* and conduct the test at 37°. Operate each apparatus at 50- rpm speed. Measure the amount of prednisone dissolved from filtered portions of the sample aliquots withdrawn at thirty minutes, at the wavelength of maximum absorbance at about 242 nm in comparison with a solution of known concentration of USP Prednisone Reference Standard.

Test Interpretation -- The apparatus is suitable if each of the individual calculated values for each apparatus is within the specified ranges shown in the Table.

Notes: An amount of alcohol not to exceed 5% of the total volume of the standard solution may be used to bring the prednisone standard into solution prior to dilution with *Dissolution medium*. The filtering method must not cause adsorptive loss of drug. Bias introduced by automated methods is to be avoided. If equipment is dedicated for use with only one apparatus (basket or paddle), then the calibration is only required for that apparatus.

These values apply only to Lot O0C056

Apparatus	Percentage of the labeled amount of prednisone dissolved at 30 minutes at 50-rpm
1	53-77
2	27-48

Founded in 1820, the United States Pharmacopeial Convention comprises representatives from colleges and national and state organizations of medicine and pharmacy. It revises and publishes *The United States Pharmacopeia* and *The National Formulary*, the legally recognized compendia of standards for drugs.

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