

Doxycycline Hyclate Tablets

» Doxycycline Hyclate Tablets contain the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of doxycycline ($C_{22}H_{24}N_2O_8$).

Packaging and storage—Preserve in tight, light-resistant containers.

Add the following:

Labeling—When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

USP Reference standards (11)—*USP Doxycycline Hyclate RS*.

Identification—Shake a suitable quantity of finely ground Tablets with methanol to obtain a solution containing the equivalent of 1 mg of doxycycline per mL, and filter. Using the filtrate as the *Test Solution*, proceed as directed for *Method II* under *Identification—Tetracyclines* (193).

Change to read:

Dissolution (711)—[NOTE—Use low-actinic glassware to prepare the solutions.]

TEST 1 • (RB 1-Aug-2009)

Medium: water; 900 mL.

Apparatus 2: 75 rpm, the distance between the blade and the inside bottom of the flask being maintained at 4.5 ± 0.5 cm during the test.

Time: 90 minutes.

Procedure—Determine the amount of $C_{22}H_{24}N_2O_8$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 276 nm of filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Doxycycline Hyclate RS in the same *Medium*.

Tolerances—Not less than 85% (*Q*) of the labeled amount of $C_{22}H_{24}N_2O_8$ is dissolved in 90 minutes.

•TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: water; 900 mL.

Apparatus 2: 50 rpm, the distance between the blade and the inside bottom of the flask being maintained at 4.5 ± 0.5 cm during the test.

Time: 30 minutes.

Standard solution: Dissolve an accurately weighed quantity of USP Doxycycline Hyclate RS in *Medium*, and dilute quantitatively and stepwise as necessary, with *Medium* to obtain a solution containing about 22 $\mu\text{g/mL}$ of doxycycline.

Test solution—Pass a portion of the solution under test through a suitable 0.45- μm filter.

Procedure—Determine the amount of $C_{22}H_{24}N_2O_8$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 276 nm on the *Test solution* in comparison with the *Standard solution*, using 0.5-cm cells and *Medium* as the blank.

Calculate the percentage of doxycycline dissolved by the formula:

$$(A_U / A_S) \times (C_S / L) \times 900 \times 100$$

where A_U and A_S are the absorbances obtained with the *Test solution* and *Standard solution*, respectively; C_S is the concentration, in mg per mL, of doxycycline in the *Standard solution*; L is the Tablet label claim in mg; 900 is the volume, in mL, of *Medium*; and 100 is the conversion factor to percentage.

Tolerances—Not less than 85% (*Q*) of the labeled amount of $C_{22}H_{24}N_2O_8$ is dissolved in 30 minutes. • (RB 1-Aug-2009)

Uniformity of dosage units (905): meet the requirements.

Water, Method I (921): not more than 5.0%.

Assay—

Mobile phase, *Diluent*, *Resolution solution*, *Standard preparation*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Doxycycline Hyclate*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of doxycycline, to a 100-mL volumetric flask, add about 75 mL of *Diluent*, sonicate for 5 minutes, shake for 15 minutes, dilute with *Diluent* to volume, and mix. Pass through a membrane filter having a 0.5- μm or finer porosity.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Doxycycline Hyclate*. Calculate the quantity, in mg, of doxycycline ($C_{22}H_{24}N_2O_8$) in the portion of Tablets taken by the formula:

$$0.1CP(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Doxycycline Hyclate RS in the *Standard preparation*; P is the designated potency, in μg of doxycycline per mg, of USP Doxycycline Hyclate RS; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.