

**§ 446.121 Doxycycline monohydrate oral dosage forms.****§ 446.121a Doxycycline monohydrate for oral suspension.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Doxycycline monohydrate for oral suspension is doxycycline monohydrate with one or more suitable and harmless buffer substances, preservatives, diluents, colorings, and flavorings. Its moisture content is not more than 3 percent. It passes the identity test for the presence of the doxycycline moiety. When prepared as directed in the labeling, each milliliter contains the equivalent of 5 milligrams of doxycycline and its pH is not less than 5.0 and not more than 6.5. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of doxycycline that it is represented to contain. The doxycycline monohydrate used conforms to the standards prescribed by § 446.21(a)(1).

(2) *Labeling.* In addition to the labeling requirements of § 432.5 of this chapter, this drug shall be labeled “doxycycline for oral suspension”.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The doxycycline monohydrate used in making the batch for potency, moisture, pH, doxycycline content, identity, and crystallinity.

(b) The batch for potency, moisture, pH, and identity.

(ii) Samples required:

(a) The doxycycline monohydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion of the well-shaken suspension to an appropriate-sized volumetric flask and dilute to volume with 0.1*N* hydrochloric acid to obtain a stock so-

lution of convenient concentration containing not less than 150 micrograms of doxycycline per milliliter (estimated). Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 0.100 microgram of doxycycline per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Reconstitute as directed in the labeling and proceed as directed in § 436.202 of this chapter, using the undiluted sample.

(4) *Identity.* Proceed as directed in § 436.308 of this chapter, except prepare the standard and sample solutions as follows: Dissolve precise amounts of the doxycycline monohydrate for oral suspension and of the doxycycline working standard in methanol and further dilute each solution to a concentration of 1 milligram of doxycycline per milliliter. Prepare the sample-standard mixed solution by mixing equal volumes of the final concentration of the sample and standard solutions. The sample and standard must each produce a major, yellow fluorescent spot with the same  $R_f$  value and the sample-standard mixed solution must show no separation of major spots.

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**§ 446.121b Doxycycline monohydrate capsules.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Doxycycline monohydrate capsules are composed of doxycycline monohydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains doxycycline monohydrate equivalent to 100 milligrams of doxycycline. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of doxycycline that it is represented to contain. The moisture content is not more than 5.5 percent. It passes the dissolution test. It passes the identity test. The doxycycline monohydrate used conforms to the standards prescribed by § 446.21.