Status: Currently Official on 13-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-3CF9976A-F17A-4434-9E24-7109F20A161F_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1460_01_01
DOI Ref: o1dd2

Allopurinol Tablets

» Allopurinol Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of allopurinol ($C_5H_4N_4O$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Allopurinol RS

Identification—Extract a quantity of finely powdered Tablets, equivalent to about 50 mg of allopurinol, by trituration with 10 mL of 0.1 N sodium hydroxide. Filter, acidify the filtrate with 1 N acetic acid, collect the precipitated allopurinol (allow 10 to 15 minutes for sufficient precipitation to occur), wash the precipitate with 3 mL of dehydrated alcohol, in portions, and finally wash with 4 mL of anhydrous ethyl ether. Allow to dry in air for 15 minutes, then dry at 105° for 3 hours: the residue so obtained meets the requirements for the *Identification* test under *Allopurinol*.

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 2: 75 rpm.

Time: 45 minutes.

Standard stock solution—Prepare a stock solution by transferring about 40 mg of USP Allopurinol RS, accurately weighed, to a 200-mL volumetric flask. Add 10 mL of 0.1 N sodium hydroxide, sonicate for about 2 minutes, shake by mechanical means for about 10 minutes, dilute with *Dissolution Medium* to volume, and mix.

Standard solution—Dilute the *Standard stock solution* with *Dissolution Medium* to obtain a solution having a concentration similar to that expected in the solution under test.

Procedure—Determine the amount of $C_5H_4N_4O$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 250 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium,* in comparison with the *Standard solution.*

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_5H_4N_4O$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩**:** meet the requirements.

Assay—[Note—Do not allow the *Mobile phase* to remain in the column overnight. After performing the procedure, flush the system with water for not less than 20 minutes, and then flush with methanol for 20 minutes.]

Mobile phase—Prepare a filtered and degassed 0.05 M solution of monobasic ammonium phosphate.

Internal standard solution—On the day of use, dissolve about 50 mg of hypoxanthine in 10 mL of 0.1 N sodium hydroxide, shake by mechanical means until dissolved (about 10 minutes), dilute with water to 50 mL, and mix.

Standard preparation—On the day of use, transfer about 50 mg of USP Allopurinol RS, accurately weighed, to a 50-mL volumetric flask, add 10 mL of 0.1 N sodium hydroxide, shake by mechanical means for 10 minutes, dilute with water to volume, and mix. Transfer 4.0 mL of this solution and 2.0 mL of *Internal standard solution* to a 200-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of allopurinol, to a 50-mL volumetric flask, add 10 mL of 0.1 N sodium hydroxide, shake by mechanical means for 10 minutes, add water to volume, and mix. [Note—From this point, conduct the remainder of the *Assay* without delay.] Filter, rejecting the first 10 mL of the filtrate. Transfer 4.0 mL of the filtrate and 2.0 mL of *Internal standard solution* to a 200-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.6 for hypoxanthine and 1.0 for allopurinol; the resolution, *R,* between the analyte and internal standard is not less than 5; and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 15 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of allopurinol ($C_5H_4N_4O$) in the portion of Tablets taken by the formula:

$$2.5C(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Allopurinol RS in the *Standard preparation;* and R_U and R_S are the peak response ratios of allopurinol to hypoxanthine obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
ALLOPURINOL TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 29(3)

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