M_{r1} = molecular weight of hydrazine, 32.05
M_{r2} = molecular weight of hydrazine sulfate, 130.12
F = unit conversion factor (from µg/mg to ppm), 1000

Acceptance criteria: NMT 10 ppm of hydrazine

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩
Analysis: Dry under vacuum at 105° for 5 h.
Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.
• **USP Reference Standards** ⟨11⟩
USP Allopurinol RS
USP Allopurinol Related Compound A RS
3-Amino-4-carboxamidopyrazole hemisulfate.
$(C_5H_6N_4O)_2 \cdot H_2SO_4$ 350.32
USP Allopurinol Related Compound B RS
5-(Formylamino)-1*H*-pyrazole-4-carboxamide.
$C_5H_6N_4O_2$ 154.13
USP Allopurinol Related Compound C RS
5-(4*H*-1,2,4-Triazol-4-yl)-1*H*-pyrazole-4-carboxamide.
$C_6H_6N_6O$ 178.15
USP Allopurinol Related Compound D RS
Ethyl 5-amino-1*H*-pyrazole-4-carboxylate.
$C_6H_9N_3O_2$ 155.15
USP Allopurinol Related Compound E RS
Ethyl 5-(formylamino)-1*H*-pyrazole-4-carboxylate.
$C_7H_9N_3O_3$ 183.16

Allopurinol Compounded Oral Suspension

DEFINITION

Allopurinol Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of allopurinol ($C_5H_4N_4O$).

Prepare Allopurinol Compounded Oral Suspension 20 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Allopurinol tablets equivalent to	2 g of allopurinol
Glycerin	5 mL
Vehicle for Oral Suspension, *NF*	45 mL
Vehicle for Oral Solution, *NF*, a sufficient quantity to make	100 mL

Select the number of tablets that contain the specified amount of allopurinol, and calculate the quantity of each ingredient required for the total amount to be prepared. Count, weigh, or measure each ingredient. Thoroughly pulverize the tablets. Mix the powdered *Allopurinol tablets* and *Glycerin* to form a smooth paste. Incorporate the *Vehicle for Oral Suspension*. Add sufficient *Vehicle for Oral Solution* to volume, and mix well. Adjust the pH, if necessary. Package and label.

SPECIFIC TESTS

• **pH** ⟨791⟩: 6.5–7.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in a tight container, and store at controlled room temperature.
• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature
• **Labeling:** Label it to state that it is to be shaken well before use, and to state the *Beyond-Use Date*.

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.