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Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: USP Monographs
DocId: GUID-6132D7EF-1FC2-4BD8-AFF8-615466FD8383_2_en-US
DOI: https://doi.org/10.31003/USPNF_M385_02_01
DOI Ref: 21jcl

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Allopurinol Compounded Oral Suspension

DEFINITION

Change to read:

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 ▲in Vehicle for Oral Suspension and Vehicle for Oral Solution▲ (USP 1-May-2020) as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Allopurinol tablets equivalent to	2 g of allopurinol
Glycerin	5 mL
Vehicle for Oral Suspension ▲▲ (USP 1-May-2020)	45 mL
Vehicle for Oral Solution, ▲▲ (USP 1-May-2020) 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 ▲in▲ (USP 1-May-2020) *Vehicle for Oral Suspension*▲and *Vehicle for Oral Solution*.▲ (USP 1-May-2020) Add sufficient *Vehicle for Oral Solution* to volume, and mix well. Adjust the pH, if necessary. Package and label.

▲Prepare Allopurinol Compounded Oral Suspension 20 mg/mL in *SyrSpend SF PH4* as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*):

Allopurinol powder	2 g
SyrSpend SF PH4,[a] a sufficient quantity to make	100 mL

[a] Fagron, St. Paul, MN.

Transfer the *Allopurinol powder* into a suitable container and triturate to form a fine powder. Wet the powder with a small amount of *SyrSpend SF PH4*, and triturate to make a smooth paste. Add increasing volumes of *SyrSpend SF PH4* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of *SyrSpend SF PH4*. Add sufficient *SyrSpend SF PH4* to bring to final volume, and mix well.▲ (USP 1-May-2020)

ASSAY

Add the following:

▲• Oral Suspension in SyrSpend SF PH4

Mobile phase: 0.05 M solution of monobasic ammonium phosphate

Standard solution: 0.02 mg/mL of USP Allopurinol RS in acetonitrile

Sample solution: Transfer 1.0 mL of Oral Suspension into a 1000-mL volumetric flask and dilute with acetonitrile to final volume. Mix well.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability.*)

Mode: LC

Detector: UV 254 nm

Columns

Guard: 4.0-mm × 3.0-mm; 5-µm packing L1

Analytical: 4.0-mm × 30-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

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System suitability

Sample: *Standard solution*

[NOTE—The retention time for allopurinol is about 6.5 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of allopurinol ($C_5H_4N_4O$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of allopurinol from the *Sample solution*

r_S = peak response of allopurinol from the *Standard solution*

C_S = concentration of USP Allopurinol RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of allopurinol in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%▲ (USP 1-May-2020)

SPECIFIC TESTS

Change to read:

• **pH** ⟨791⟩

▲**Oral Suspension in Vehicle for Oral Suspension** and **Vehicle for Oral Solution:**▲ (USP 1-May-2020) 6.5–7.5

▲**Oral Suspension in *SyrSpend SF PH4*:** 3.5–4.5▲ (USP 1-May-2020)

ADDITIONAL REQUIREMENTS

Change to read:

• **PACKAGING AND STORAGE:** ▲Package in tight, light-resistant containers. Store the Oral Suspension in Vehicle for Oral Suspension and Vehicle for Oral Solution at controlled room temperature. Store the Oral Suspension in *SyrSpend SF PH4* at controlled room temperature or in a refrigerator.▲ (USP 1-May-2020)

Change to read:

• **BEYOND-USE DATE**

▲**Oral Suspension in Vehicle for Oral Suspension and Vehicle for Oral Solution:**▲ (USP 1-May-2020) NMT 60 days after the date on which it was compounded when stored at controlled room temperature

▲**Oral Suspension in *SyrSpend SF PH4*:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator▲ (USP 1-May-2020)

• **LABELING:** Label it to state that it is to be shaken well before use, and to state the *Beyond-Use Date*.

Add the following:

▲• **USP REFERENCE STANDARDS** ⟨11⟩

USP Allopurinol RS▲ (USP 1-May-2020)

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Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ALLOPURINOL COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(6)

Current DocID: GUID-6132D7EF-1FC2-4BD8-AFF8-615466FD8383_2_en-US

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