

Status: Currently Official on 16-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocId: GUID-E8FCD852-409E-457B-8356-6A7308282104_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M60600_01_01
 DOI Ref: rz5ru

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Papain Tablets for Topical Solution

DEFINITION

Papain Tablets for Topical Solution contain NLT 100.0% of the labeled potency.

ASSAY

• PROCEDURE

Dibasic sodium phosphate solution: Dissolve 7.1 g of anhydrous dibasic sodium phosphate in water to make 1 L. Add 1 drop of toluene as a preservative.

Citric acid solution: Dissolve 10.5 g of citric acid monohydrate in water to make 1 L. Add 1 drop of toluene as a preservative.

Casein substrate: Disperse 1 g of Hammersten-type casein in 50 mL of *Dibasic sodium phosphate solution*. Place in a boiling water bath for 30 min with occasional stirring. Cool to room temperature, and add *Citric acid solution* to adjust to a pH of 6.0 ± 0.1 . Stir the solution rapidly and continuously during the addition of the *Citric acid solution* to prevent precipitation of the casein. Dilute with water to 100 mL. Prepare fresh daily.

Buffer solution: Dissolve 3.55 g of anhydrous dibasic sodium phosphate in 400 mL of water in a 500-mL volumetric flask. Add 7.0 g of disodium edetate and 3.05 g of cysteine hydrochloride monohydrate. Adjust with 1 N hydrochloric acid or 1 N sodium hydroxide to a pH of 6.0 ± 0.1 , dilute with water to volume, and mix. Prepare fresh daily.

Trichloroacetic acid solution: 300 mg/mL of reagent-grade trichloroacetic acid. This solution may be stored at room temperature.

Standard solution: Weigh accurately 100 mg of [USP Papain RS](#) in a 100-mL volumetric flask, and add *Buffer solution* to dissolve. Dilute with *Buffer solution* to volume, and mix. Transfer 2.0 mL of this solution to a 50-mL volumetric flask, dilute with *Buffer solution* to volume, and mix. Use within 30 min after preparation.

Sample solution: Place a counted number of Papain Tablets for Topical Solution, equivalent to about 600,000 USP Units of Papain, in a 100-mL volumetric flask, dissolve in *Buffer solution*, dilute with *Buffer solution* to volume, and mix. Transfer 2.0 mL of this solution to a 50-mL volumetric flask, dilute with *Buffer solution* to volume, and mix.

Analysis: Into each of 12 test tubes (18 × 150 mm) pipet 5.0 mL of *Casein substrate*. Place in a water bath at 40°, and allow 10 min to reach bath temperature. The tests are run in duplicate except for the blanks. Into each of two of the tubes labeled S_1 pipet 1.0 mL of the *Standard solution* and 1.0 mL of *Buffer solution*. Mix by swirling, note zero time, insert the stopper, and replace in the bath. Into each of two other tubes labeled S_2 pipet 1.5 mL of the *Standard solution* and 0.5 mL of *Buffer solution*, and proceed as before. Repeat this procedure for two tubes labeled S_3 to which 2.0 mL of the *Standard solution* is added, and for two tubes labeled U_2 to which 1.5 mL of the *Sample solution* and 0.5 mL of *Buffer solution* are added. After 60 min, accurately timed, add to all 12 tubes 3.0 mL of *Trichloroacetic acid solution*, and shake vigorously. With the four tubes to which neither the *Standard solution* nor the *Sample solution* was added, prepare blanks by pipeting, respectively, 1.0 mL of the *Standard solution* and 1.0 mL of *Buffer solution*; 1.5 mL of the *Standard solution* and 0.5 mL of *Buffer solution*; 2.0 mL of the *Standard solution*; and 1.5 mL of the *Sample solution* and 0.5 mL of *Buffer solution*. Replace all tubes in the 40° water bath for 30–40 min to allow the precipitated protein to coagulate fully. Pass through filter paper of medium pore size, discarding the first 3 mL of the filtrate (filtrates used are clear). Read the absorbances, at 280 nm, of the filtrates of all solutions against their respective blanks. Plot the absorbance readings for S_1 , S_2 , and S_3 against the enzyme concentration of each corresponding level.

By interpolation from the standard curve, calculate the potency, in USP Units, of the number of Papain Tablets for Topical Solution taken:

$$\text{Result} = A \times C \times F$$

A = activity of the [USP Papain RS](#) (Units/mg)

C = concentration from the standard curve (mg/mL)

F = $100 \times (50/2) \times (10/1.5)$, dilution factor

Acceptance criteria: NLT 100.0% of the labeled potency

PERFORMANCE TESTS

- [DISINTEGRATION <701>](#): NMT 15 min at 23 ± 2°

SPECIFIC TESTS

- [COMPLETENESS OF SOLUTION <641>](#)

Sample solution: Prepare a solution of 50 Papain Tablets for Topical Solution in 500.0 mL of water, and allow to stand for 4 h.

Analysis: Pass the *Sample solution* through two superimposed, matched-weight, 47-mm-diameter membrane filters of 0.8-µm pore size, and wash the residue by rinsing the flask at the sides of the holder with water. Dry both filters in a desiccator under vacuum, over phosphorus pentoxide for 6–18 h. Weigh the filters separately, and subtract the weight of the lower filter from that of the upper filter.

Acceptance criteria: NMT 50 mg (1 mg/Tablet) difference in weights

- [MICROBIAL ENUMERATION TESTS <61>](#) AND [TESTS FOR SPECIFIED MICROORGANISMS <62>](#): It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

- [pH <791>](#)

Sample solution: 1 Tablet in 10 mL of water

Acceptance criteria: 6.9–8.0

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store in a cool place.

- [USP REFERENCE STANDARDS <11>](#)

[USP Papain RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PAPAIN TABLETS FOR TOPICAL SOLUTION	Maria Monagas Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-E8FCD852-409E-457B-8356-6A7308282104_1_en-US

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