

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: NF Monographs
DocId: GUID-827427A3-A55E-4A21-8002-0DDE35F13067_6_en-US
DOI: https://doi.org/10.31003/USPNF_M34770_06_01
DOI Ref: 75if4

© 2025 USPC
Do not distribute

Gelatin

Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (♦) to specify this fact.

DEFINITION

Purified protein obtained from collagen of animals ♦ (including fish and poultry) , by partial alkaline and/or acid hydrolysis, and/or enzymatic hydrolysis, or by thermal hydrolysis.

The hydrolysis leads to gelling or non-gelling grades. This monograph covers both the gelling grades and non-gelling grades (called also hydrolyzed gelatin).

IDENTIFICATION

- ♦ A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A

[NOTE—Compare the spectra of the test specimen and [USP Gelatin RS](#) over the range from 800 to 3500 cm^{-1} . Disregard any peak at about 1403 cm^{-1} .]♦

- B.

Sample solution: Dissolve 1.00 g in carbon dioxide-free water at about 55°, dilute with the same solvent to 100 mL, and keep at 55°. Save the unused portion of this solution for use in the test for pH.

Analysis: To 2 mL of the *Sample solution* add 0.05 mL of a 125-g/L solution of [copper sulfate pentahydrate](#). Mix, and add 0.5 mL of an 85-g/L solution of [sodium hydroxide](#).

Acceptance criteria: A violet color is produced.

- C.

Sample: 0.5 g

Analysis: Place the *Sample* in a test tube of about 15-mm internal diameter, and add 10 mL of water. Allow to stand for 10 min, heat at 60° for 15 min, and keep the tube upright at 2°–8° for 6 h. Invert the tube.

Acceptance criteria: The contents do not flow out immediately for gelling grades. The contents immediately flow out for non-gelling grades.

- D. FOR NON-GELLING GRADES

Medium: pH 6.8 phosphate buffer. Mix 77.3 mL of a 71.5-g/L solution of [disodium hydrogen phosphate dodecahydrate](#) with 22.7 mL of a 21-g/L solution of [citric acid](#).

Sample: 0.5 g

Color reagent: Prepare immediately before use. Dissolve 1.0 g of [dimethylaminobenzaldehyde](#) in 3.5 mL of [perchloric acid](#) [600 g/L of perchloric acid (HClO_4)].

Analysis: Place the *Sample* in a 250-mL bottle. Add 10 mL of water and 5 mL of sulfuric acid. Place the bottle, partly but not completely closed (for example, using a watch glass), in an oven at 105° for 4 h. Allow to cool, and add 200 mL of water. Adjust with a 200-g/L solution of [sodium hydroxide](#) to a pH of 6.0–8.0. Place 2 mL of the solution in a test tube, and add 2 mL of oxidizing reagent (14-g/L solution of [chloramine T](#) in the *Medium*; prepare immediately before use). Mix, and allow to stand for 20 min. Add 2 mL of *Color reagent*, and slowly add 6.5 mL of 2-propanol). Mix, and place in a water bath at 60° for about 15 min.

Acceptance criteria: A red to violet color develops.

SPECIFIC TESTS

- [pH \(791\)](#)

Sample: Use the *Sample solution* prepared in *Identification B*.

Acceptance criteria: 3.8–7.6 at 55°

- [WATER CONDUCTIVITY \(645\)](#)

Sample: 1.0% solution at $30 \pm 1.0^\circ$

Analysis: Determine without the use of the temperature compensation.

Acceptance criteria: NMT $1 \text{ mS} \cdot \text{cm}^{-1}$

Change to read:

• **SULFUR DIOXIDE**

Sample: 25.0 g

Titrimetric system

Mode: Direct titration

Titrant: [0.1 N sodium hydroxide VS](#)

Endpoint detection: Visual

Analysis: Introduce 150 mL of water into the flask (see A in [Figure 1](#)), and pass carbon dioxide through the whole system for 15 min at a rate of 100 mL/min. To 10 mL of hydrogen peroxide solution [30 g/L of hydrogen peroxide (H_2O_2)] add 0.15 mL of [bromophenol blue TS](#). Add

▲*Titrant*▲ (ERR 1-Nov-2020) until a violet-blue color is obtained, without exceeding the endpoint. Place the solution in the test tube (D). Without interrupting the stream of carbon dioxide, remove the funnel (B), and introduce through the opening into the flask (A) the *Sample* with the aid of 100 mL of water. Add through the funnel 80 mL of diluted hydrochloric acid [73 g/L of hydrogen chloride (HCl)], and boil for 1 h. Open the tap of the funnel, stop the flow of carbon dioxide, and also stop the heating and the cooling water. Transfer the contents of the test tube with the aid of a little water to a 200-mL wide-necked, conical flask. Heat on a water bath for 15 min, and allow to cool. Add 0.1 mL of [bromophenol blue TS](#), and titrate with *Titrant* until the color changes from yellow to violet-blue.

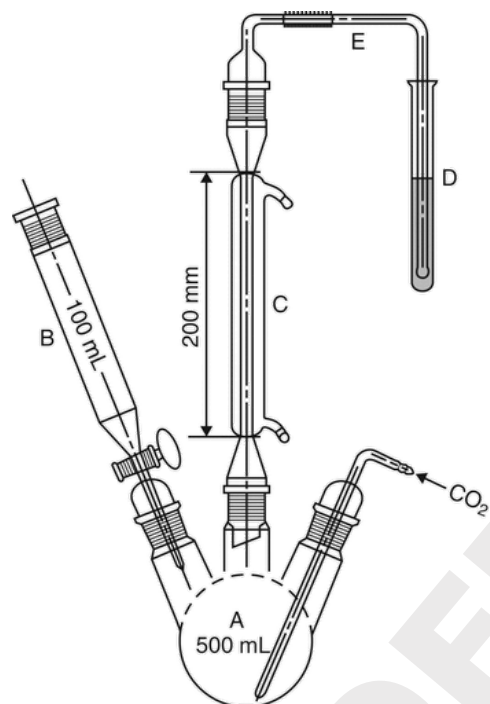


Figure 1. Apparatus for determination of sulfur dioxide.

Carry out a blank titration, and calculate the content of sulfur dioxide, in ppm:

$$\text{Result} = [(V_S - V_B) \times (\text{▲}N\text{▲ (ERR 1-Nov-2020)} / W)] \times 32,030$$

V_S = volume of ▲*Titrant*▲ (ERR 1-Nov-2020) consumed by the *Sample* (mL)

V_B = volume of ▲*Titrant*▲ (ERR 1-Nov-2020) consumed by the blank (mL)

▲ N ▲ (ERR 1-Nov-2020) = actual ▲normality▲ (ERR 1-Nov-2020) of the *Titrant*▲ (ERR 1-Nov-2020)

W = weight of the *Sample* (g)

Acceptance criteria: NMT 50 ppm

• **PEROXIDES**