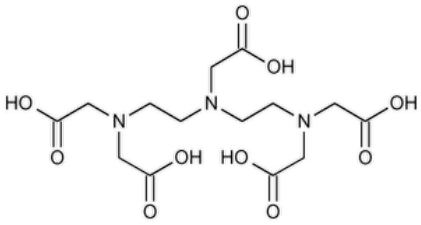
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-A527405E-FE7B-4D6D-B90D-9603DE36CE8E_4_en-US
DOI: https://doi.org/10.31003/USPNF_M62300_04_01
DOI Ref: 5m5ci

Pentetic Acid



$C_{14}H_{23}N_3O_{10}$ 393.35

Glycine, *N*,*N*-bis[2-[bis(carboxymethyl)amino]ethyl].

Diethylenetriaminepentaacetic acid CAS RN®: 67-43-6; UNII: 7A314HQM0I.

» Pentetic Acid contains not less than 98.0 percent and not more than 100.5 percent of $C_{14}H_{23}N_3O_{10}$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Pentetic Acid RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Residue on ignition ⟨281⟩: not more than 0.2%.

Limit of nitrilotriacetic acid—

Cupric acetate solution—Dissolve 20 g of cupric acetate in a mixture of 800 mL of water and 10 mL of glacial acetic acid. Adjust with 1 N sodium hydroxide to a pH of 4.2, dilute with water to obtain 1000 mL of solution, and filter.

Mobile phase—Prepare a mixture of 1600 mL of water, 40 mL of glacial acetic acid, 30.4 mL of 0.5 M dodecyltriethylammonium phosphate, and 20 mL of *Cupric acetate solution.* Adjust with 1 N sodium hydroxide to a pH of 4.0, dilute with water to obtain 2000 mL of solution, filter through a filter having a 0.5-µm or finer porosity, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Stock standard solution—Transfer about 50 mg of nitrilotriacetic acid, accurately weighed, to a 100-mL volumetric flask, dilute with *Cupric acetate solution* to volume, and mix.

Standard solution—Transfer 1.0 mL of the *Stock standard solution* to a 25-mL volumetric flask, dilute with *Cupric acetate solution* to volume, and mix. This solution contains about 0.02 mg of nitrilotriacetic acid per mL.

Test solution—Transfer about 2 g of Pentetic Acid, accurately weighed, to a 100-mL volumetric flask. Add about 70 mL of *Cupric acetate solution*, and swirl to dissolve. Sonicate, if necessary, to dissolve. Dilute with *Cupric acetate solution* to volume, and mix.

Resolution solution—Transfer 1.0 mL of the *Stock standard solution* to a 25-mL volumetric flask, dilute with *Test solution* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 290-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1 that has been highly deactivated (carbon loading of about 30%). The flow rate is about 1 mL per minute. Equilibrate the column by passing, in sequence, water, methanol, and water for about 15 minutes each, and then *Mobile phase* for about 45 minutes. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between pentetic acid and nitrilotriacetic acid is not less than 2.0, and the relative retention times are about 0.6 for pentetic acid and 1.0 for nitrilotriacetic acid. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 5.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, and measure the responses for the major peaks. Calculate the percentage of nitrilotriacetic acid in the portion of Pentetic Acid taken by the formula:

$$10{,}000(C/W)(r_U/r_S)$$

of which C is the concentration, in mg per mL, of nitrilotriacetic acid in the *Standard solution*, W is the weight, in mg, of Pentetic Acid taken to

prepare the *Test solution*, and r_U and r_S are the nitrilotriacetic acid peak responses obtained from the *Test solution* and the *Standard solution*, respectively. The limit is 0.1%.

Iron—Using 1.5 g of specimen, proceed as directed in the test for *Iron* under *Edetic Acid.* The color of the test solution is not deeper than that of the solution containing the standard iron solution (0.01%).

Assay—Transfer about 200 mg of Pentetic Acid, accurately weighed, to a 125-mL conical flask, add 50 mL of water and 1.5 mL of 1 N sodium hydroxide, and swirl to dissolve the specimen. Add 10 mL of 0.1 N ammonium thiocyanate, and mix. Add about 40 mL of methyl ethyl ketone, mix, and allow the layers to separate. Titrate with 0.05 N ferric ammonium sulfate VS, stirring continuously. As the titration proceeds, the aqueous phase turns from colorless to yellow, and the organic phase remains colorless. As the endpoint is approached, stop the titration, mix, and allow the layers to separate. Add 0.1-mL increments of 0.05 N ferric ammonium sulfate VS, mixing and allowing the layers to separate after each addition, until the organic layer turns from colorless to pink. Each mL of 0.05 N ferric ammonium sulfate consumed is equivalent to 19.668 mg of $C_{14}H_{23}N_3O_{10}$.

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

Topic/Question	Contact	Expert Committee
PENTETIC ACID	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(3)

Current DocID: GUID-A527405E-FE7B-4D6D-B90D-9603DE36CE8E_4_en-US
DOI: https://doi.org/10.31003/USPNF_M62300_04_01
DOI ref: 5m5ci