Taurine

Type of Posting	Revision Bulletin
Posting Date	22–Feb–2019
Official Date	01–Mar–2019
Expert Committee	Non-Botanical Dietary Supplements
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Non-Botanical Dietary Supplements Expert Committee has revised the Taurine monograph. The purpose for the revision is to address the comments received from the industry that some of the *System Suitability* requirements were not consistently met by all manufacturers. A Notice of Intent to Revise has been published on USP website (https://www.uspnf.com/notices/taurine-nitr) to address these concerns. This issue may result in a non-compliance that may cause significant product shortages in critical categories such as parenteral nutrition.

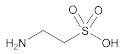
The following changes will be published in the Revision Bulletin:

- In the *Assay* the *Suitability requirements* for *Column efficiency* and *Relative standard deviation* are changed from NLT 10,000 to NLT 6000 and from NMT 2.0% to NMT 3%, respectively.
- The requirement for the correlation coefficient of the linear regression line in the *Assay* is changed from NLT 0.995 to NLT 0.99.
- Clarification is added to the *Analysis* section of the *Assay* procedure to indicate that the *Sample solution* should be analyzed with three injections to obtain the average value of taurine peak area.

The Taurine Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Fatkhulla Tadjimukhamedov**,** Scientific Liaison to the Non-Botanical Dietary Supplements (301-230-3216 or fkt@usp.org).

Taurine



$C_2H_7NO_3S$ 125.15
Taurine
Ethanesulfonic acid, 2-amino-;
2-Aminoethane-1-sulfonic acid [107-35-7].

DEFINITION
Taurine contains NLT 98.0% and NMT 102.0% of taurine ($C_2H_7NO_3S$), calculated on the dried basis.

IDENTIFICATION
- **A. Infrared Absorption** ⟨197K⟩
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solutions*, as obtained in the *Assay*.

ASSAY

Change to read:

- **Procedure**

Solution A: Water adjusted with acetic acid to a pH of 3.0.
Mobile phase: Acetonitrile and *Solution A* (80:20)
Standard stock solution: Prepare a solution containing 1.0 mg/mL of USP Taurine RS in *Mobile phase*.
Standard solutions: Using the *Standard stock solution* prepare three *Standard solutions* with concentrations of 0.4, 0.5, and 0.6 mg/mL of USP Taurine RS in *Mobile phase*.
Sample solution: 0.5 mg/mL of Taurine in *Mobile phase*
Chromatographic system
(See *Chromatography* ⟨621⟩*, System Suitability*.)
Mode: LC
Detector: Evaporative light-scattering detector (ELSD)
Drift tube temperature: 55° or optimize according to the manufacturer's recommendations to achieve optimal signal-to-noise ratio
Nebulizer gas: Nitrogen
Nebulizer gas flow rate: 1.5 L/min or optimize according to the manufacturer's recommendations to achieve optimal signal-to-noise ratio
Column: 3-mm × 10-cm; 2.5-µm packing L104
Column temperature: 25°
Flow rate: 0.4 mL/min
Injection volume: 5 µL
System suitability
Sample: *Standard solution* at 0.5 mg/mL
Suitability requirements
Column efficiency: NLT ▲6000▲ (RB 1-Mar-2019) theoretical plates
Tailing factor: NMT 1.5
Relative standard deviation: NMT ▲3%▲ (RB 1-Mar-2019)
Analysis
Samples: *Standard solutions* and *Sample solution*
Plot the logarithms of the taurine peak areas against the logarithms of taurine concentrations, in mg/mL, in the three *Standard solutions* and establish a calibration curve by least-squares regression. The correlation coefficient for the regression line is NLT ▲0.99. Inject the *Sample solution* three times and obtain the average value of taurine peak areas.▲ (RB 1-Mar-2019) Using the logarithm of the ▲average▲ (RB 1-Mar-2019) taurine peak area from the *Sample solution*, calculate the logarithm of taurine concentration from the calibration curve and calculate the concentration, *C*, in mg/mL, of taurine in the *Sample solution* by taking the antilog of the result.
Calculate the percentage of taurine ($C_2H_7NO_3S$) in the portion of Taurine taken:

$$\text{Result} = (C/C_U) \times 100$$

C = concentration of Taurine in the *Sample solution* (mg/mL), determined from the calibration curve
C_U = concentration of Taurine in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES
- **Residue on Ignition** ⟨281⟩**:** NMT 0.3%
- **Chloride and Sulfate** ⟨221⟩**,** *Chloride*

Standard: 0.50 mL of 0.020 N hydrochloric acid
Sample: 0.7 g of Taurine
Acceptance criteria: NMT 0.05%

- **Chloride and Sulfate** ⟨221⟩**,** *Sulfate*

Standard: 0.25 mL of 0.020 N sulfuric acid
Sample: 0.8 g of Taurine
Acceptance criteria: NMT 0.03%

- **Iron** ⟨241⟩**:** NMT 30 ppm
- **Related Compounds**

Sample solution: 10 mg/mL of Taurine in water
Standard solution: 0.05 mg/mL of USP Taurine RS in water, an equivalent concentration of about 0.5% of the *Sample solution*
Chromatographic system
(See *Chromatography* ⟨621⟩*, General Procedures, Thin-Layer Chromatography*.)
Mode: TLC
Adsorbent: 0.25-mm layer of chromatographic silica gel mixture
Application volume: 5 µL
Developing solvent system: Butyl alcohol, glacial acetic acid, and water (3:1:1)
Spray reagent: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)
Analysis: Dry the plate at 80° for 30 min. Spray the plate with *Spray reagent*, and heat at 80° for about 10 min. Examine the plate under white light. [NOTE—The R_F value for the taurine spots should be about 0.2.]
Acceptance criteria: No secondary spot of the *Sample solution* is larger or more intense than the principal spot of the *Standard solution*.
Individual impurities: NMT 0.5%

SPECIFIC TESTS
- **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 3 h.
Acceptance criteria: NMT 0.3%

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

USP Taurine RS