

TANABE U.S.A., INC.

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Phenylalanine

USP XXI I I Reference No. PHE-50217

L-Phenylalanine [63-91-2].

Phenylalanine contains not less than 98.5 percent and not more than 101.5 percent of C₉H₉NO₂, as phenylalanine, calculated on the dried basis.

Phenylalanine: White, odorless crystals, having a slightly bitter taste. Sparingly soluble in water; very slightly soluble in methanol, in alcohol, and in dilute mineral acids.

Packaging and storage Preserve in well-closed containers. USP Reference standards (11) Ñ USP t-Phenylalanine RS. Identification, Infrared Absorption (197K).

Specific rotation (781S): between Ñ32.7; and Ñ34 7;. Test solution 20 mg per mL, in water.

pH (791): between 5.4 and 6.0, in a solution (1 in 100).

Loss on drying (731) Dry it at 105; for 3 hours: it loses not more than 0.3% of its weight.

Residue on ignition (281): not more than 0.4%.

Chloride (221) A 0.73-g portion shows no more chloride than corresponds to 0.50 mL of 0.020 N hydrochloric acid (0.05%).

Sulfate (221) A 0.33-g portion shows no more sulfate than corresponds to 0.10 mL of 0.020 N sulfuric acid (0.03%).

Arsenic (211): 1.5 ppm. Iron (241~: 0.003%. Heavy metals, Method I (23 1): 0.001 5%.

Organic volatile impurities, Method I (467): meets the requirements.

Assay Transfer about 160 mg of Phenylalanine, accurately weighed, to a 125-mL flask, dissolve in a mixture of 3 mL of formic acid and 50 mL of glacial acetic acid, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 16.52 mg of C₉H₉NO₂.