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21 Authors

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22 Date of Revision

4 May 2017.

Leucine

1 Nonproprietary Names

BP: Leucine

JP: L-Leucine

PhEur: Leucine

USP–NF: Leucine

2 Synonyms

α-Aminoisocaproic acid; 1-α-aminoisocaproic acid; (*S*)–2-amino-4-methylpentanoic acid; 2–amino-4-methylpentanoic acid; L-2-amino-4-methylvaleric acid; 2–amino-4-methylvaleric acid; α-amino-γ-methylvaleric acid; 1,2-amino-4-methylvaleric acid; D L-leucine; L;L-leucine; Leu; leucinum; 4-methylnorvaline.

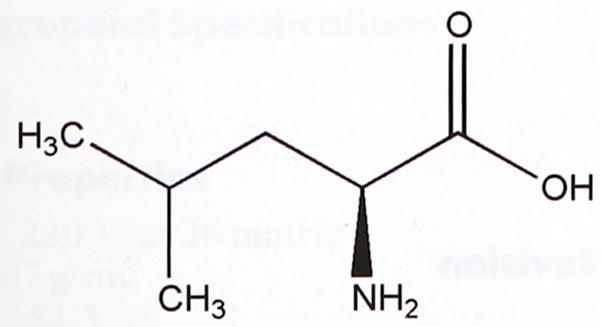
3 Chemical Name and CAS Registry Number

L-Leucine [61-90-5]

4 Empirical Formula and Molecular Weight

$C_6H_{13}NO_2$ 131.17

5 Structural Formula



6 Functional Category

Antiadherent; flavoring agent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Leucine is used in pharmaceutical formulations as a flavoring agent.[1] It has been used experimentally as an antiadherent to improve the deagglomeration of disodium cromoglycate microparticles and other compounds in inhalation preparations;[2–4] and as a tablet lubricant.[5,6] Leucine copolymers have been shown to successfully produce stable drug nanocrystals in water.[7]

8 Description

Leucine occurs as a white or almost off-white crystalline powder or shiny flakes.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for leucine.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters	+	+	–
Optical rotation	+14.5° to +16.0°	+14.5° to +16.5°	+14.9° to +17.3°
pH	5.5–6.5	–	5.5–7.0
Appearance of solution	+	+	–
Chloride	≤0.021%	≤200 ppm	≤0.05%
Sulfate	≤0.028%	≤300 ppm	≤0.03%
Ammonium	≤0.02%	≤0.02%[a]	–
Ninhydrin-positive substances	–	≤0.2%[a]	–
Iron	–	≤10 ppm	≤30 ppm
Heavy metals	≤20 ppm	–	≤15 ppm
Arsenic	≤2 ppm	–	–
Related substances	+	–	+
Loss on drying	≤0.30%	≤0.5%	≤0.2%
Residue on ignition	≤0.10%	–	≤0.4%
Sulfated ash	–	≤0.1%	–
Assay	≥98.5%	98.5–101.5%	98.5–101.5%

(a) For each impurity.

10 Typical Properties

Density 1.293 g/cm^3

Dissociation constant

pK_{a1} = 2.36;

pK_{a2} = 9.60.

Isoelectric point 6.04

Solubility Soluble in acetic acid, ethanol (99%), and water. Practically insoluble in ether.