

Valerian

Valerian consists of the subterranean parts of *Valeriana officinalis* Linn é (Fam. Valerianaceae) including the rhizome, roots, and stolons. It contains not less than 0.5 percent of volatile oil and not less than 0.05 percent of valerenic acid ($C_{15}H_{22}O_2$), calculated on the dried basis.

Packaging and storage— Store in tight containers, protected from light and moisture, and store at room temperature.

Labeling— The label states the Latin binomial and, following the official name, the parts of the plant contained in the article.

Botanic characteristics—

Macroscopic— Rhizome erect, entire or usually cut longitudinally, up to 5 cm in length and up to 3 cm in diameter, yellowish gray to pale grayish brown, base elongated or compressed, covered by and merging with numerous roots; apex usually bearing a cup-shaped scar from aerial parts, stem bases rarely present; in longitudinal section, pith exhibiting a central cavity traversed by septa.

Roots numerous, slender, almost cylindrical, and of the same color as the rhizome, about 10 cm in length and up to 3 mm in diameter; a few filiform, fragile secondary roots; fracture short. Stolon pale yellowish gray, showing prominent nodes separated by longitudinally striated internodes each 2 to 5 cm in length; fracture fibrous.

Histology— Root, with piliferous layer, of papillosed cells, some being developed into root hairs; exodermis, or a single layer of quadrangular to polygonal cells with suberized walls and containing globules of volatile oil; outer cortex of two to four layers of resin-containing cells with thin or collenchymatous, sometimes suberized walls; inner cortex of numerous layers of polygonal to rounded cells filled with starch. Starch granules simple or compound; simple granules rounded, 5 to 15 μ m in diameter, sometimes showing a cleft or stellate hilum; compound granules with two to six components, up to 20 μ m in diameter. Endodermis consisting of a single layer of suberized, tangentially elongated cells, pericycle continuous, starch-filled; parenchyma surrounding the phloem zone; cambium frequently indistinct; vascular bundles forming an interrupted ring surrounding the starch-filled cells. Rhizome in transverse section, different from the root, its structure being complicated by the presence of numerous vascular bundles from root and stolon; epidermis and exodermis partially replaced by poorly developed periderm; central pith wide,

including cavities of various sizes, the larger ones being separated by plates of partially sclerified tissue.

Identification—

A: Transfer about 0.2 g of freshly powdered Valerian to a test tube, add 5 mL of methylene chloride, shake several times, and allow to stand for 5 minutes. Filter, wash the filter with 2 mL of methylene chloride, and combine the filtrate and washings in one container. Heat the combined filtrate and washings on a water bath for the minimum time required to evaporate the solvent, and dissolve the residue in 0.2 mL of methylene chloride. To about 0.1 mL of this solution, add 3 mL of a mixture of equal volumes of glacial acetic acid and 25% hydrochloric acid, and shake several times: a blue color develops within 15 minutes.

B: The retention time of the valerenic acid peak in the chromatogram of the Test solution corresponds to that in the chromatogram of the Standard solution, as obtained in the test for Content of valerenic acid.

[Total ash](#) [561](#) : not more than 12.0%.

[Acid-insoluble ash](#) [561](#) : not more than 5.0%.

[Water content](#) [561](#) : not more than 12.0%.

Extractable matter— Mix 2 g of Valerian, carefully dried at 40 °C and coarsely powdered, with 20 mL of 70 percent alcohol, and allow to stand for 2 hours, shaking frequently. Filter, evaporate 5 mL of the filtrate on a water bath to dryness, and dry the residue at 105 °C. The weight of the dried residue is not less than 100 mg (20%).

[Volatile oil](#) [561](#) : not less than 0.5%, 100 g of freshly and coarsely comminuted Valerian being used.

[Pesticide residues](#) [561](#) : meets the requirements.

[Foreign organic matter](#) [561](#) : not more than 2.0%.

[Microbial enumeration](#) [2021](#) — The total bacterial count does not exceed 10⁵ cfu per g, the total combined molds and yeasts count does not exceed 10³ cfu per g, bile-tolerant Gram-negative

bacteria does not exceed 10³, and it meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

Content of valerenic acid—

Mobile phase— Prepare a filtered and degassed mixture of methanol and dilute phosphoric acid (1 in 200) (80:20). Make adjustments if necessary (see System Suitability under [Chromatography 621](#)).

Standard solution— Dissolve an accurately weighed quantity of [USP Valerenic Acid RS](#) in 70 percent alcohol to obtain a solution having a known concentration of about 0.05 mg per mL.

Test solution— Transfer about 2 g of Valerian, reduced to a powder and accurately weighed, to a flask, add 40.0 mL of 70 percent alcohol, and shake by mechanical means for 2 hours at room temperature. Centrifuge, and use the clear extract as the Test solution.

Chromatographic system—The liquid chromatograph is equipped with a 225-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute.

Chromatograph the Standard solution, and record the peak responses as directed for Procedure: the tailing factor for the valerenic acid peak is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the Standard solution and the Test solution into the chromatograph, record the chromatograms, and measure the responses for the valerenic acid peaks. Calculate the percentage of valerenic acid (C₁₅H₂₂O₂) in the portion of Valerian taken by the formula:

$$2000(C / W)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Valerenic Acid RS](#) in the Standard solution; W is the weight, in mg, of Valerian taken to prepare the Test solution; and r_U and r_S are the valerenic acid peak responses obtained from the Test solution and the Standard solution, respectively: not less than 0.05% is found.