

## Powdered Garlic Extract

Powdered Garlic Extract is prepared from fresh Garlic bulbs by extraction with alcohol. The ratio of the starting crude plant material to Powdered Extract is between 9.5:1 and 13.5:1. It contains not less than 4.0 percent of alliin (C<sub>6</sub>H<sub>11</sub>NO<sub>3</sub>S). It may contain added Powdered Garlic or other suitable substances.

**Packaging and storage**— Preserve in tight containers, in a cool place, protected from light.

**Labeling**— The label states the Latin binomial and, following the official name, the part of the plant from which the article was prepared. The label also indicates the content of alliin, the extracting solvent or solvent mixture used for preparation, and the ratio of the starting crude plant material to Powdered Extract. It meets the requirements for Labeling under [Botanical Extracts](#)

[565](#) .

### **Identification**—

A: [Thin-Layer Chromatographic Identification Test](#) [201](#) —

**Test solution**— Transfer an accurately weighed quantity of Powdered Extract, equivalent to about 5 mg of alliin, to a suitable container. Add 40 mL of a mixture of methanol and water (1:1), and shake until the powder is fully dispersed. Centrifuge, and decant the supernatant into a round-bottom flask. Concentrate to a small volume (about 5 mL) using a rotary evaporator.

Standard solution A, Standard solution B, Application volume, Developing solvent system, and

**Procedure**— Proceed as directed for Identification test A under [Garlic](#).

B: The retention time of the alliin 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 alliin.

[Microbial enumeration](#) [2021](#) — The total bacterial count does not exceed 10,000 cfu per g, and the total combined molds and yeasts count does not exceed 1000 cfu per g. It meets the requirements of the tests for absence of Salmonella species and Escherichia coli.

[Water content](#) [561](#) : not more than 5.0%.

[Heavy metals, Method I](#) [231](#) : 0.001%.

### **Content of alliin**—

0.045 M Phosphate buffer, 0.05 M Phosphate buffer, 0.01 M Carboxymethoxylamine hemihydrochloride solution, Derivatization reagent, Mobile phase, Standard solution, and Chromatographic system— Proceed as directed for Content of alliin under [Garlic](#).

**Test solution**— Transfer about 0.10 g of Powdered Extract, accurately weighed, to a 50-mL volumetric flask, add 30 mL of 0.01 M Carboxymethoxylamine hemihydrochloride solution, and shake until the Powdered Extract is fully dispersed. Dilute with 0.01 M Carboxymethoxylamine hemihydrochloride solution to volume, and mix. Centrifuge, transfer 5 mL of the clear supernatant to a 10-mL volumetric flask, dilute with 0.01 M Carboxymethoxylamine hemihydrochloride solution to volume, and mix. Using a volumetric syringe, transfer 0.1 mL of this solution to a septum-capped vial, add 0.5 mL of the Derivatization reagent, and mix. Allow a reaction time of not less than 2 minutes before injection into the chromatograph.

**Procedure**— Proceed as directed for Content of alliin under [Garlic](#). Calculate the percentage of alliin in the portion of Powdered Extract taken by the formula:

$$60(C/W)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Alliin RS in the Standard solution; W is the weight, in g, of Powdered Extract taken to prepare the Test solution; and  $r_U$  and  $r_S$  are the sums of the peak responses for the alliin diastereomers obtained from the Test solution and the Standard solution, respectively.

[Alcohol content, Method II](#) [611](#) : not more than 0.5%.

**Other requirements**— It meets the requirements for Packaging and Storage and Pesticide Residues under [Botanical Extracts](#) [565](#) .

**Alliinase activity**—

0.045 M Phosphate buffer, 0.05 M Phosphate buffer, 0.01 M Carboxymethoxylamine hemihydrochloride solution, Derivatization reagent, Mobile phase, Standard solution, and

**Chromatographic system**— Proceed as directed for Content of alliin under [Garlic](#).

**Test solution**— Incubate 200 mg of Powdered Extract with 20 mL of water at room temperature for 5 minutes. Immediately after incubation, add 80.0 mL of 0.01 M Carboxymethoxylamine hemihydrochloride solution, mix, and centrifuge. Using a volumetric syringe, transfer 0.1 mL of

this solution to a septum-capped vial, add 0.5 mL of the Derivatization reagent, and mix. Allow a reaction time of not less than 2 minutes before injection into the chromatograph.

**Procedure**— Proceed as directed for Content of alliin under [Garlic](#); the area of the alliin peak obtained from the chromatogram of the Test solution is not more than 1% of the area of the alliin peak obtained from the chromatogram of the Standard solution.