U.S. PHARMACOPEIA

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Shellac

» Shellac is obtained by the purification of Lac, the resinuous secretion of the insect *Laccifer Lacca Kerr* (Fam. Coccidae). Orange Shellac is produced either by a process of filtration in the molten state, or by hot solvent process, or both. Orange Shellac may retain most of its wax or be dewaxed, and may contain lesser amounts of the natural color than originally present. Bleached (White) Shellac is prepared by dissolving the Lac in aqueous sodium carbonate, bleaching the solution with sodium hypochlorite and precipitating the Bleached Shellac with 2 N sulfuric acid. Removal of the wax, by filtration, during the process results in Refined Bleached Shellac. Shellac conforms to the specifications in the accompanying table.

	Acid value (on dried basis)	Loss on drying	Wax
Orange Shellac	between 68 and 76	not more than 2.0%	not more than 5.5%
Dewaxed Orange Shellac	between 71 and 79	not more than 2.0%	not more than 0.2%
Regular Bleached Shellac	between 73 and 89	not more than 6.0%	not more than 5.5%
Refined Bleached Shellac	between 75 and 91	not more than 6.0%	not more than 0.2%

Packaging and storage— Preserve in well-closed containers, preferably in a cold place.

Labeling— Label it to indicate whether it is bleached or is orange, and whether it is dewaxed or wax-containing.

Identification— To 50 mg of Shellac add a few drops of a mixture of 1 g of ammonium molybdate and 3 mL of sulfuric acid: a green color is produced, and it becomes lilac on standing for 5 minutes.

Acid value— Dissolve about 2 g of finely ground Shellac, accurately weighed, in 50 mL of alcohol that has been neutralized to phenolphthalein with 0.1 N sodium hydroxide, add additional phenolphthalein TS, if necessary, and titrate with 0.1 N sodium hydroxide VS to a pink endpoint. [NOTE—For orange Shellac, titrate slowly, stirring vigorously, until a glass rod dipped into the titrated solution produces a color change when touched to a drop of thymol blue TS on a spot plate.] Express the acid value in terms of the number of mg of potassium hydroxide required per g of dried Shellac.

Loss on drying ⟨ 731 ⟩ **—** Dry it at 41 ± 2°, in a well-ventilated oven, for 24 hours.

Heavy metals, *Method II* ⟨ 231 ⟩ : 0.001%.

Wax— Transfer about 10 g of finely ground Shellac, accurately weighed, and 2.50 g of sodium carbonate to a 200-mL, tall-form beaker. Add 150 mL of hot water, immerse the beaker in a boiling water bath, and stir until the solid is dissolved. Cover the beaker with a watch glass, and maintain the heat for 3 hours more, without agitation. Remove the beaker to a cold water bath. When the wax has floated to the surface, pass the solution through medium-speed quantitative ashless filter paper, transferring the wax to the paper, and wash the filter with water. Pour 5 to 10 mL of alcohol onto the filter to facilitate drying. Wrap the paper loosely in a larger piece of filter paper, bind with a piece of fine wire, and dry with the aid of gentle heat. Extract with chloroform in a suitable continuous extraction apparatus for 2 hours, using a weighed flask to receive the extracted wax and solvent. Evaporate the solvent, and dry the wax at 105° to constant weight.

Rosin— Dissolve 2 g by shaking with 10 mL of dehydrated alcohol, add slowly, with shaking, 50 mL of solvent hexane, wash with two successive 50-mL portions of water, filter the washed alcohol–solvent hexane solution, and evaporate to dryness. To the residue add 2 mL of a mixture of 1 volume of liquefied phenol, ½ volume of dehydrated alcohol, and 2 volumes of solvent hexane. Stir, and transfer a portion of the solution to a cavity of a color-reaction plate. Fill an adjacent cavity with a mixture of 1 volume of bromine and 4 volumes of solvent hexane, and cover both cavities with an inverted watch glass: no purple or deep indigo-blue color is produced in or above the liquid containing the residue.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
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