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Pygeum

DEFINITION

Pygeum consists of the bark of *Prunus africana* (Hook f.) Kalkman (*Pygeum africanum* Hook f.) (Fam. Rosaceae). It contains NLT 9.0% of extractable matter.

IDENTIFICATION

• A. THIN-LAYER CHROMATOGRAPHY

Standard solution A: 10 mg/mL of [USP Pygeum Extract RS](#) in chloroform

Standard solution B: 1 mg/mL of USP β -Sitosterol RS in chloroform

Sample solution: Transfer 10 g of the powdered plant material to a Soxhlet apparatus. Extract with 150 mL of methylene chloride for 4 h. Evaporate the extract under vacuum to dryness. Dissolve the residue with 10 mL of methylene chloride.

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Adsorbent: 0.25-mm layer of chromatographic silica gel (TLC plates)

Application volume: 10 μ L

Developing solvent system: Methylene chloride

Derivatization reagent: Sulfuric acid and water (1:1)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Develop in a saturated chamber for NLT 15 cm, and dry the plate in a stream of air. Treat with *Derivatization reagent*, heat the plate at 100° for 10 min, and examine under white light.

Acceptance criteria: The chromatogram of the *Sample solution* shows one red-violet zone turning to grayish-brown near the origin that corresponds in color and R_f value to that in the chromatogram of *Standard solution A*; one red-violet zone turning to grayish-brown at an R_f about 0.08, corresponding in color and R_f value to that in the chromatogram of *Standard solution B*; further upward, a grayish-brown zone may be present, corresponding in color and R_f value to that in the chromatogram of *Standard solution A*. Other colored zones of varying intensities may be observed in the chromatogram of the *Sample solution*.

COMPOSITION

• EXTRACTABLE MATTER

Analysis: Extract 2.00 g of the powdered material in a Soxhlet apparatus with 150 mL of alcohol for 6 h. Evaporate the solution to dryness under vacuum, and dry the residue at 105° for 24 h.

Acceptance criteria: NLT 9.0% of extractable matter

CONTAMINANTS

- [ARTICLES OF BOTANICAL ORIGIN, Limits of Elemental Impurities \(561\)](#): Meets the requirements
- [ARTICLES OF BOTANICAL ORIGIN, Pesticide Residue Analysis \(561\)](#): Meets the requirements

SPECIFIC TESTS

• BOTANICAL CHARACTERISTICS

Macroscopic: Bark pieces consist of long fragments of variable dimensions, from only a few cm to 1 m long with a thickness varying from a few mm to 1–2 cm. The color is brown, more or less dark on the external surface; light brown to red-brown on the internal surface. The external face of the bark presents a very dark and fissured rhytidome that in the samples of old trees is fragmented in more or less square plaques of about 1–5 cm. The thickness varies from 1 mm in young plants or branches to 5–8 mm in old plants. The outer surface may also be covered with whitish lichens or thin filamentous moss. The internal face of the bark, under the rhytidome, is clearer and has a reddish coloration, with a long fibrous break, from reddish to light brown or dark brown in color, often presenting concentric stratification cracks. The internal surface presents small wrinkles.

Microscopic: The transverse section of the bark presents a suberized bed of variable thickness depending on the age of the plant, consisting of multiple layers of small, square cells with the walls of moderate thickness. It presents a cortical parenchyma of more or less round cells, with a few apparent formations of very thin-walled sclereids, definitely sharp. Often, in the parenchyma, there are groups of cells containing oxalate druses; a few bigger cells with highly thickened walls can also be observed. It shows a liber with phloem zones and medullary rays. The phloemical portions contain groups of fibrous cells with highly thickened walls, as well as phloemical and parenchymal elements, sometimes containing druses of oxalate. The medullary rays are of conical shape, larger on the external surface and thinner on the internal side; they can also contain druses of oxalate.

- [ARTICLES OF BOTANICAL ORIGIN, Foreign Organic Matter\(561\)](#): NMT 5.0%
- [LOSS ON DRYING \(731\)](#): Dry at 60° for 15 h; it loses NMT 10.0% of its weight.
- [ARTICLES OF BOTANICAL ORIGIN, Total Ash\(561\)](#): NMT 10.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, 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.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Pygeum Extract RS](#)
[USP β-Sitosterol RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
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Chromatographic Database Information: [Chromatographic Database](#)

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