Ku Shen Extract (Sophora flavescens) – Oxymatrine 10–98%

Sophora flavescens · Fabaceae

DOCUMENT	PRODUCT CODE	DOCUMENT NO.	REVISION	PRODUCT FORM
Technical Data Sheet	AP1148	TDS-AP1148	1.0 · 24 October 2026	Standardized Extract

1 Product description

Ku Shen extract is produced from the root of Sophora flavescens (Fabaceae family) and supplied as a standardized extract powder, standardized to Oxymatrine. Available grades: 10%, 30%, 98%. Typical sourcing: China. Intended for B2B formulation in nutraceuticals & supplements, cosmetics & personal care, pharmaceutical.

10% 30% 98%

2 Identification

Botanical source	*Sophora flavescens* (Fabaceae)
Common name(s)	Ku Shen
Plant part used	Root
Typical origin	China
Marker compound	Oxymatrine (Other alkaloids)
Manufacturing process	Water and/or hydro-alcoholic (ethanol) extraction, concentration and spray-drying; the solvent system for each grade is stated on the CoA
Standardisation	10–98% (HPLC)
Assay method	HPLC
Pharmacopoeia & standards	Chinese Pharmacopoeia

3 Specification

PARAMETER	SPECIFICATION	METHOD
Appearance	Brown to yellowish-brown fine powder	Visual
Odour	Characteristic	Organoleptic
Identification	Conforms (HPTLC / HPLC fingerprint vs. reference)	HPTLC / HPLC
Assay – Oxymatrine	Not less than the labelled grade (10%, 30%, 98%)	HPLC
Loss on drying	≤ 5.0%	USP ‹731›
Total ash	≤ 5.0%	USP ‹561›
Particle size	≥ 95% through 80 mesh (180 µm)	USP ‹786›
Bulk density	Report (typically 0.40–0.70 g/mL)	USP ‹616›
Residual solvents	Complies with ICH Q3C / USP ‹467›	GC-HS
Lead (Pb)	≤ 3.0 mg/kg	ICP-MS
Arsenic (As)	≤ 2.0 mg/kg	ICP-MS
Cadmium (Cd)	≤ 1.0 mg/kg	ICP-MS
Mercury (Hg)	≤ 0.1 mg/kg	ICP-MS
Pesticide residues	Complies with USP ‹561› and Regulation (EC) No 396/2005	GC-MS/MS, LC-MS/MS
Aflatoxins	B1 ≤ 2 µg/kg; sum of B1, B2, G1, G2 ≤ 4 µg/kg	HPLC-FLD
Total aerobic microbial count	≤ 10,000 cfu/g	USP ‹2021›
Yeasts & moulds	≤ 1,000 cfu/g	USP ‹2021›

Escherichia coli	Absent in 10 g	USP ‹2022›
Salmonella spp.	Absent in 25 g	USP ‹2022›
Staphylococcus aureus	Absent in 10 g	USP ‹2022›

Limits above are the standard release specification for this product class. Each lot is released against its Certificate of Analysis, which is the governing document and is available on request.

4 Grades & pack sizes

GRADE	SKU PREFIX	PACK SIZES
10%	AP1148-10	Sample (50 g) · 250 g · 1 Kg · 5 Kg · 25 Kg
30%	AP1148-30	Sample (50 g) · 250 g · 1 Kg · 5 Kg · 25 Kg
98%	AP1148-98	Sample (1 g) · 50 g · 250 g · 1 Kg

Made-to-order grades: 30%.

5 Packaging

- Samples: food-grade HDPE jar or aluminium-laminate pouch.
- 250 g – 1 Kg: food-grade LDPE bag sealed in an aluminium-laminate pouch.
- 5 Kg – 25 Kg: double food-grade LDPE bags in a fibre drum or HDPE pail.
- Packaging may vary by lot and is stated on the packing list.

6 Storage & shelf life

- Shelf life: 24 months from date of manufacture in the original, unopened packaging.
- Store in a cool (below 25 °C), dry place, protected from light.
- Hygroscopic: reseal immediately after use and minimise exposure to humid air.

7 Applications

Industries	Nutraceuticals & Supplements, Cosmetics & Personal Care, Pharmaceutical
Formulation focus	Immune Support, Skin & Hair Care
Traditional systems	Traditional Chinese Medicine

Use levels depend on the finished product and the target market. The customer is responsible for establishing safe and permitted use levels and for any claims made on finished products.

8 Regulatory & compliance

- Pharmacopoeia / standard references: Chinese Pharmacopoeia.
- Allergen information: not derived from a source listed in Annex II of Regulation (EU) No 1169/2011.
- Regulatory status for food, supplement, cosmetic or pharmaceutical use (e.g. EU novel food, US NDI/GRAS, FSSAI) must be confirmed by the customer for the intended market and use.

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