Red Yeast Rice Extract (Monascus purpureus) – Monacolin K 0.4–3%

Monascus purpureus · Monascaceae

DOCUMENT	PRODUCT CODE	DOCUMENT NO.	REVISION	PRODUCT FORM
Technical Data Sheet	AP0763	TDS-AP0763	1.0 · 24 October 2026	Fungal & Fermented Extract

1 Product description

Red Yeast Rice extract is produced from the fermented rice of Monascus purpureus (Monascaceae family) and supplied as a fungal / fermented ingredient, standardized to Monacolin K. Available grades: 0.4%, 3%. Typical sourcing: China, Japan. Intended for B2B formulation in nutraceuticals & supplements.

0.4% 3%

2 Identification

Botanical source	*Monascus purpureus* (Monascaceae)
Common name(s)	Red yeast rice
Plant part used	Other
Typical origin	China, Japan
Marker compound	Monacolin K (Fungal polyketides)
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	0.4–3% (HPLC)
Assay method	HPLC
Pharmacopoeia & standards	USP, EFSA opinion / novel food

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 – Monacolin K	Not less than the labelled grade (0.4%, 3%)	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
0.4%	AP0763-0P4	Sample (50 g) · 250 g · 1 Kg · 5 Kg · 25 Kg
3%	AP0763-3	Sample (50 g) · 250 g · 1 Kg · 5 Kg · 25 Kg

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
Traditional systems	Medicinal mushrooms

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: USP, EFSA opinion / novel food.
- **Pharmaceutical active:** Contains a pharmacologically active substance that is regulated as a medicine (often prescription-only) in many markets. Supplied only to qualified businesses after a compliance review.
- 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.

This Technical Data Sheet is issued by CHOLAD PRIVATE LIMITED (trading as Extrakte), C 22/4, 2nd & 3rd Floor, Sector-57, Noida-201301, Uttar Pradesh, India · +91 817 8117 600 · choladco@gmail.com · extrakte.com. The information is given in good faith and reflects our current knowledge of the product; it does not constitute a warranty of properties for any specific application. Refer to the Safety Data Sheet **SDS-AP0763** for hazard, handling and transport information. Certificates of Analysis are issued per lot and are available on request.