สารสกัดแห้งมังคุด (MANGKHUT DRY EXTRACT)

Mangosteen Rind Dry Extract

Category Antidiarrheal, wound healing, anti-inflammatory.

Mangosteen Rind Dry Extract is prepared from the powdered Mangosteen Rind by extraction with *ethanol*. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of α -mangostin ($C_{24}H_{26}O_6$); the labelled amount of α -mangostin is not less than 14.0 per cent, calculated on the dried basis.

Description Brownish yellow powder; hygroscopic.

Packaging and storage Mangosteen Rind Dry Extract shall be kept in tightly closed containers, protected from light, and stored in a cool and dry place.

Labelling The label on the container states (1) the amount of α -mangostin; (2) the expiration date.

Identification

A. The chromatogram of the Assay preparation shows several peaks, one of which corresponds to that of the Standard preparation, as obtained in the *Assay* (Fig. 1).

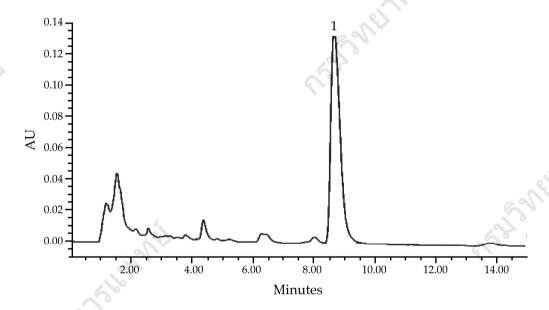


Fig. 1 HPLC Chromatogram of Mangosteen Rind Dry Extract Showing α -Mangostin (1)

B. Carry out the test as described in the "Thin-Layer Chromatography" (Appendix 3.1), using a high-performance plate with *silica gel GF254* as the coating substance and a mixture of 90 volumes of *chloroform* and 5 volumes of *methanol* as the mobile phase and allowing the solvent front to ascend 8 cm above the line of application. Apply separately to the plate as bands of 6 mm, 3 mL each of solutions (A) and (B). Prepare solution (A) by dissolving 10 mg of the sample, in powder, in 1 mL of *methanol*. For solution (B), dissolve 1 mg of α -mangostin in 2 mL of *methanol*. After removal of the plate, allow it to dry in air, and examine under ultraviolet light (254 nm), marking the quenching bands. The chromatogram obtained from solution (A) shows a quenching band (hR_f value 60 to 64), corresponding to the α -mangostin band obtained from solution (B). Other seven quenching bands are also observed. Subsequently

examine the plate under ultraviolet light (366 nm); the band due to α -mangostin is dark fluorescent. One dark and three blue fluorescent bands are also observed. Spray the plate with *anisaldehyde TS and* heat at 110° for about 10 minutes. The band due to α -mangostin is yellow. One brown and other two yellow bands are also observed (Fig. 2).

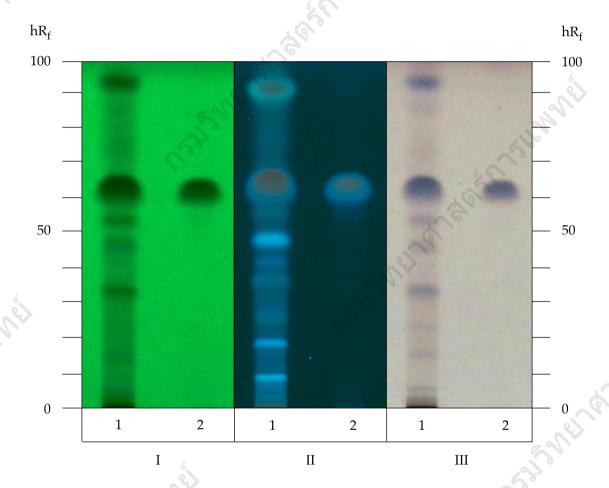


Fig. 2 Thin-Layer Chromatogram of Mangosteen Rind Dry Extract

1 = solution(A)

2 = solution (B)

I = detection under UV light (254 nm)

II = detection under UV light (366 nm)

III = dectection with *anisaldehyde TS*

Loss on drying Not more than 10.0 per cent w/w after drying at 105° to constant weight (Appendix 4.15).

Assay Carry out the determination as described in the "Liquid Chromatography" (Appendix 3.5).

Mobile phase Prepare a mixture of 70 volumes of *water* and 30 volumes of *methanol*. Make adjustments if necessary.

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Standard preparations Dissolve a suitable quantity of α -Mangostin RS, accurately weighed, in sufficient methanol to obtain a stock solution having a known concentration of about 500 µg of α -mangostin per mL. Dilute the solution quantitatively, and stepwise with methanol to obtain six solutions having known concentrations of about 10, 20, 30, 40, 50, and 60 µg per mL of α -mangostin.

Assay preparation Transfer about 50 mg of Mangosteen Rind Dry Extract, accurately weighed, to a 100-mL volumetric flask, add 25 mL of methanol, sonicate until completely dissolved, and adjust with methanol to volume. Mix well and filter through a membrane having a 0.45-µm membrane filter.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (15 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (4.6 µm), equipped with a similarly packed guard column, (b) Mobile phase at a flow rate of about 1.2 mL per minute, and (c) an ultraviolet photometer set at 243 nm. To determine the suitability of the chromatographic system, chromatograph Standard preparation, and record the peak response as directed under Procedure and Calculation: the relative standard deviation for replicate injections is not more than 2.0 per cent.

Procedure Separately inject about 20 µL each of Standard preparations into the chromatograph, record the chromatograms and measure the responses for α -mangostin peaks. Plot the readings and draw the standard curve of best fit: the curve shows the correlation coefficient of not less than 0.999. Inject about 20 µL of Assay preparation into the chromatograph, record the chromatogram, and measure the response for α -mangostin peak.

Calculation By reference to the standard curve, calculate the content of α -mangostin $(C_{24}H_{26}O_6)$ in the portion of the Extract taken.

15 ST SMELL OF THE OWNER OF ST Other requirements Complies with the requirements described under "Extracts" (Appendix 1.16H).