สารสกัดแห้งกระท่อม (KRATHOM DRY EXTRACT)

Kratom Dry Extract

Category Analgesic, antidiarrheal.

Kratom Dry Extract is prepared from the powdered Kratom by extraction with water. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labelled amount of mitragynine ($C_{23}H_{30}N_2O_4$); the labelled amount of mitragynine is not less than 10.0 per cent, calculated on dried basis.

Description Brownish yellow powder.

Packaging and storage Kratom 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 mitragynine; (2) the expiration date.

Identification 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).

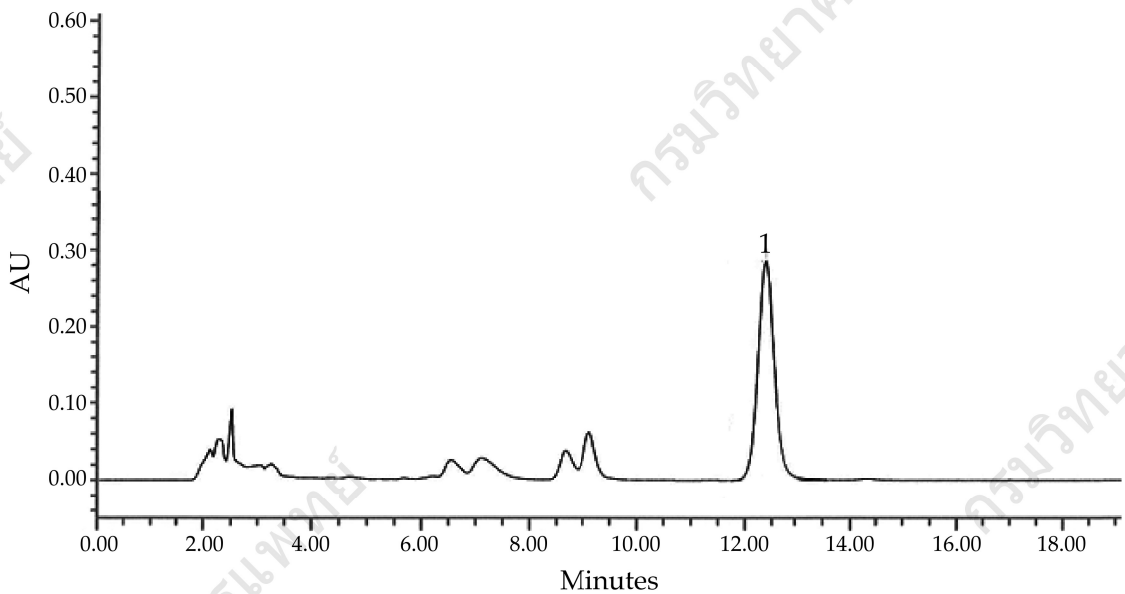

Fig. 1 HPLC Chromatogram of Kratom Dry Extract Showing Mitragynine (1)

Loss on drying Not more than 6.0 per cent w/w after drying at 105° to constant weight, use 1 g (Appendix 4.15).

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

Diluent Prepare a mixture of 8 volumes of *methanol* and 2 volumes of a 0.1 per cent v/v solution of *glacial acetic acid*.

Buffer solution Dissolve 1.54 g of *ammonium acetate* in 500 mL of *water*, adjust with *glacial acetic acid* to pH 6.0, and dilute to 1000.0 mL.

Mobile phase Prepare a mixture of 65 volumes of *acetonitrile* and 35 volumes of *Buffer solution*.

Standard preparations Dissolve a suitable quantity of Mitragynine RS in sufficient *Diluent* to obtain a stock solution having a known concentration of about 100 µg of mitragynine per mL. Dilute the solution quantitatively and stepwise with the same solvent to obtain six solutions of 10, 20, 40, 60, 80, and 100 µg of mitragynine per mL. Filter through a membrane having a 0.45-µm porosity.

Assay preparation Transfer about 25 mg of Kratom Dry Extract, in *fine powder* and accurately weighed, to a 50-mL volumetric flask and add 35 mL of *Diluent*. Sonicate for 30 minutes, allow to cool to room temperature, and adjust to volume with the same solvent. Centrifuge the resulting solution at 3218 × *g* (5000 rpm) for 5 minutes. Use the supernatant and filter through a membrane having a 0.45-µm porosity.

Chromatographic system The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 4.6 mm) packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (5 µm), (b) *Mobile phase* at a flow rate of 1.0 mL per minute, and (c) an ultraviolet photometer set at 225 nm.

To determine the suitability of the chromatographic system, chromatograph *Standard preparation* having a known concentration of 60 µg per mL, 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. The symmetry factor for mitragynine peak is not more than 1.5.

Procedure and **Calculation** Separately inject about 20 µL of *Standard preparations* into the chromatograph, record the chromatograms, and measure the responses for the mitragynine peaks. Plot the readings and draw the standard curve of best fit: the curve shows the correlation coefficient of not less than 0.995. Inject about 20 µL of *Assay preparation* into the chromatograph, record the chromatogram, and measure the response for the mitragynine peak. By reference to the standard curve, calculate the content of mitragynine ($C_{23}H_{30}N_2O_4$) in the portion of the Extract taken.

Other requirements Complies with the requirements described under “Extracts” (Appendix 1.16H).