ORYZAGAMMA™ MILKY

This product is an emulsion of oil in water type obtained by emulsifying γ-oryzanol (ferulic acid ester of triterpene alcohol) from seed coats of *Oryza sativa* Linnè〔*Gramineae*〕. It contains not less than 4.0% and not more than 6.0% of γ-oryzanol ($C_{40}H_{58}O_4$: 602.90).

Manufacturing method

Emulsify 40kg of glycerin, 25kg of purified water, 15kg of caprylic/capric acid triglyceride, 12kg of glycerol esters of fatty acids, 5kg of γ-oryzanol and 3kg of soybean phospholipid with a homogenizer. Filter if necessary, and obtain the product.

Raw material 100kg → Product about 100kg

Description

This product is a milky white to light yellowish milky white, viscous liquid. It has slightly characteristic odor.

Identification

- γ-Oryzanol
  Determine the absorption spectrum of a solution of this product in ethanol (1→5000): it exhibits maximum at about 325nm.

- Caprylic/Capric Acid Triglyceride
  To 10g of this product add 50mL of 1mol/L potassium hydroxide-ethanol TS, and warm on a water bath for 2 hours under a reflux condenser. After cooling, add 50mL of water, transfer to a separator, acidify with hydrochloric acid, extract with three 20mL portions of ether with thorough shaking. To the ether layer add 5g of anhydrous sodium sulfate, allow to stand for 20 minutes, filter, and evaporate the ether from the filtrate. To 0.1 g of the residue add 3mL of boron trifluoridemethanol TS, boil on a water bath for 2 minutes, after methylesterifying, add 30mL of ether, transfer to a separator, and shake with 20mL of water. Separate the ether layer, add 3g of anhydrous sodium sulfate, allow to stand for 20 minutes, filter, and evaporate the ether from the filtrate. Dissolve the residue in 5mL of hexane, and use this solution as the test solution. Take separately 0.05g each of caprylic acid for gas chromatography and capric acid for gas chromatography, dissolve in 3mL of boron trifluoride-methanol TS, and use a solution of methylester compound in hexane obtained in the same manner as standard caprylic acid and capric acid solution for gas chromatography.

  Perform the test with 5μL each of the test solution and the standard solution as directed under Gas Chromatography according to the following operating conditions: the principal peaks of the test solution, excluding the solvent peak, coincide with the principal peaks of the standard solution.

Operating conditions:

Detector: A hydrogen flame-ionization detector.

Column: A column 3 to 4mm in inside diameter and 1m in length, packed with 15% of methyl silicone (GE-SE 30) for gas chromatography coated on siliceous earth for gas chromatography 149 to 177μm in particle diameter.

Column temperature: Constant temperature of about 120 ° C.

Carrier gas and flow rate: Nitrogen. Constant volumes of about 40mL per minute.

- Glycerol esters of fatty acids

  Proceed as directed in Caprylic/capric acid triglyceride, and perform the test as directed under Gas Chromatography, column temperature is a constant temperature of about 200 ° C, and use the standard substance as standard oleic acid instead of caprylic acid for gas chromatography and capric acid for gas chromatography: the peaks of the test solution coincide with the principal peaks of the standard solution.

- Glycerin

  Transfer 10g of this product to a separator, add 50mL of ethanol, shake well and allow to stand. Separate the ethanol layer, and evaporate the ethanol. To the residue add 0.5g of potassium bisulfate, and heat: an acrolein-like, irritating odor is perceptible.

- Soybean Phospholipid

  Take 1 g of this product in Kjeldahl flask, add 5g of powdered potassium sulfate, 0.5g of cupric sulfate and 20mL of sulfuric acid, and heat carefully on asbestos. After the solution becomes blue and transparent, heat further for 2 hours. After cooling, add 20mL of water, and to 5mL of the solution add 10mL of ammonium molybdate TS, and heat: a yellow precipitate is formed.

Purity

- Heavy metals

  Proceed with 1.0g of this product according to Method 2, and perform the test: the limit is not more than 20ppm. Prepare the control solution with 2.0mL of Standard Lead Solution.

- Arsenic

  Prepare the test solution with 1.0g of this product according to Method 3, and perform the test: the limit is not more than 2ppm.

Assay

- γ-Oryzanol

  Weigh accurately about 0.03g of this product, dissolve in ethanol to make exactly 100mL, and filter if necessary. Read the absorbance A of this solution at the maximum wavelength at about 325nm.

Calculate on amount of γ-oryzanol according to the following formula from absorbance A.

Amount(%) of γ-Oryzanol = (A×100)/(W×363)

A: Absorbance of the test solution

W: Weight(g) of this product

These standards and test method are referred to General Notices and General Tests, Processes and Apparatus of The Japanese Standards of Quasi-drug Ingredients, unless otherwise specified.

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