

ORYZAGAMMA™-V

This product is obtained from seed coats of *Oryza sativa* Linné (*Gramineae*), and consists chiefly of ferulic acid ester of triterpene alcohol. It contains, when dried, not less than 98% of cycloartenyl ferulate ($C_{40}H_{58}O_4$: 602.90).

Manufacturing method

Remove the rind of seed of *Oryza sativa* Linné (*Gramineae*), clean the unpolished rice, obtain the rice bran, and extract oil, very small quantity of ingredients from the rice bran. After removing the gum, wax and free fatty acid in extracted oil, then extract crude γ -oryzanol with using n-hexane (JIS K8848), absolute ethanol (monopoly, absolute, first class), sodium hydroxide (JIS K8576) and sulfuric acid (JIS K8951). Recrystallize crude γ -oryzanol with using n-hexane (JIS K8848) to obtain the product.

Raw material: Rice Bran 1000kg \longrightarrow product: about 0.5 – 1.0kg

Description

This product is a white to light yellow crystals or crystalline powder, it is odorless or having slightly characteristic odor.

Identification

- γ -Oryzanol

Determine the absorption spectrum of a solution of this product in heptane (1 \rightarrow 100,000): it exhibits maximum at $231 \pm 2\text{nm}$, $291 \pm 2\text{nm}$, and $315 \pm 2\text{nm}$.

- γ -Oryzanol

To 0.01 g of this product add 10 mL of potassium hydroxide-ethanol TS, and dissolve by warming: a yellow color develops.

- γ -Oryzanol

Dissolve 0.01 g of this product in 2 mL of acetone, and add 0.1 mL of a ferric chloride-ethanol solution (1 \rightarrow 50): a yellowish green to green color develops.

Purity

- Heavy metals

Take 1.0g of this product, prepare the test metals according to method 2: the limit is not more than 10ppm. Use 1.0mL of standard lead solution as the control solution.

- Arsenic

Take 1.0g of this product, prepare the test solution according to method 3, and perform the test: the limit is not more than 2ppm.

Loss on drying: 3.0% max. (1g, 105°C, 1 hour)

Residue on ignition: 0.5% max. (Method 1, 1g)

Assay

Cycloartenyl ferulate

Weigh accurately 0.01g of this product, previously dried at 105°C for 1 hour, dissolve in n-heptane to make exactly 100mL. Take 10mL of this solution, and add n-heptane to make exactly 100mL. Determine the absorbance A of this solution at the maximum wavelength at about 315nm in a 10mm cell.

$$\text{Amount (mg) of cycloartenyl ferulate (C}_{40}\text{H}_{58}\text{O}_4: 602.90) = (A/363) \times 10,000$$

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.

Product Name	: ORYZAGAMMA™ -V
Expiry date	: 2 years from date of manufacturing
Manufacturer	: ORYZA OIL & FAT CHEMICAL CO., LTD. 1 Aza Numata Kitagata Kitagata-cho Ichinomiya-city, Aichi-pref. 493-8001 JAPAN

Published on October 22, 2014

Revised on September 17, 2021