



ORYZA OIL & FAT CHEMICAL CO.,LTD.

1 Aza Numata Kitagata Kitagata-cho Ichinomiya-city, Aichi-prefecture 493-8001 JAPAN
Phone:+81-586-86-5141 Facsimile:+81-586-86-6191
URL/http://www.oryza.co.jp/ E-mail:info@oryza.co.jp

PRODUCT STANDARD

PRODUCT NAME : **GAMMA ORYZANOL** (for Medicine use in Japan)

This product is extracted and refined from the rice bran of *Oryza sativa* Linne (Gramineae).
Dried product contains minimum of 98 % γ -Oryzanol ($C_{40}H_{58}O_4$).

Appearance

White or slightly yellow colored crystal or crystalline powder. It has no smell or slightly unique smell.

Certification Test

- (1) To 10 mg of this product, add 10 ml of 3.5 w/v% Potassium hydroxide-ethanol. After heating, a yellow color develops.
- (2) Dissolve 10 mg of this product with 2 ml of ethyl acetate and, in addition, mix 0.2 mg of sulfuric acid and wave it, the liquid presents yellow - orange. And add 1 ml of acetic anhydride to this liquid, the liquid gradually turns into green through purple from purple-red.
- (3) The absorbance at the maximum wave length of n-Heptane solution (1 \rightarrow 100,000) is at 229~233 nm, 289~293 nm, and 313~317 nm.

Loss on Drying

Max. 0.5 % (Japanese Pharmacopoeia, 1g)

Ignition Residue

Max. 0.1 % (Japanese Pharmacopoeia, 1g)

Purity Test

(1)Heavy Metals (as Pb)

Max. 20 ppm (Japanese Pharmacopoeia, 1g, The Second Method)

(2)Arsenic (as As₂O₃)

Max. 2 ppm (Japanese Pharmacopoeia, 1g, The Third Method, Apparatus B)

Quantitative Analysis

Dissolve 0.05 g of this product on heating for 20 minutes at 70~80 °C after adding about 70 ml of n-Heptane. After having got cold to room temperature, make 100 ml correctly by adding n-Heptane. Take 2 ml and make 100 ml by adding n-Heptane. Measure the absorbance E at the length of the layer 10 mm and the wave length 315nm.

$$\text{Quantity of } \gamma\text{- Oryzanol (\%)} = \frac{E \times 50000 \times 100 \times 100}{W \times 359 \times (100-D)}$$

E: Absorbance

W: γ - Oryzanol weight (mg) used for measurement.

D: Loss on drying (%)

359: extinction coefficient of γ - Oryzanol (1%, 1cm)

Established Date	September 26, 2015
Revised Date	October 28, 2016
Specification No.	Z-628TO