

# ORYZAFERULIX

This product is ferulic acid (4-hydroxy-3-methoxycinnamic acid) obtained from seed coats of *Oryza sativa* Linné (*Gramineae*). It contains not less than 98.0% of ferulic acid ( $C_{10}H_{10}O_4$ : 194.19).

## 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 ferulic acid with using n-hexane (JIS K8848), sodium hydroxide (JIS K8576) and sulfuric acid (JIS K8951). Recrystallize ferulic acid with using ethanol to obtain the product.

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

## Description

This product is a white to slight yellowish brown powder. It is odorless or having slightly characteristic odor.

## Identification

- Ferulic acid

Determine the absorption spectrum of a solution of this product in methanol (1 $\rightarrow$ 100000): it exhibits maximum at 236nm and 322nm.

- Phenol compounds

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

- Phenol compounds

Dissolve 0.01 g of this product in 2 mL of aceton, and add 0.1 mL of a ferric chloride-ethanol solution (1 $\rightarrow$ 50): a reddish brown 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 1ppm.

**Loss on drying** : 0.5% max. (1g, 105°C, 3 hour)

**Residue on ignition** : 0.1% max. (Method 1, 5g)

**Melting point** : 171 to 174°C (Method 1)

## Assay

Ferulic acid : 98.0% min.

Weigh accurately 0.02g of this product, previously dried at 105°C for 1 hour, dissolve in ethanol to make exactly 50mL and use this solution as the test solution. Separately, weigh accurately 0.02g of the standard of ferulic acid, dissolve in ethanol to make 50mL and use this solution as the standard solution. Perform the test with exactly 5  $\mu$  L each of the test solution and the standard solution directed under Liquid Chromatography according to the following conditions, determine the peak areas, AT and AS, of ferulic acid, and calculate the amount of ferulic acid by the following equation.

$$\text{Amount of Ferulic acid (\%)} = \frac{\text{Amount of Standard (g)} \times \text{Purity of Standard (\%)}}{\text{Amount of Test Sample (g)} \times 100} \times \frac{A_T}{A_S} \times 100$$

A<sub>T</sub>: Peak area of Test solution

A<sub>S</sub>: Peak area of Standard solution

### Operating Conditions:-

Detector: An ultraviolet absorption photometer (wavelength: 322nm)

Column : A stainless steel column 4.6mm in inside diameter and 25cm in length, packed with octadecylsilanized silica gel for liquid chromatography (3  $\mu$  m in particle size)

Column temperature: A constant temperature of about 35°C

Mobile phase: Methanol : 0.1% phosphoric acid = 50 : 50

Flow rate: 10mL/min.

## Bacterial Count

Take 5g of this solution, make 50mL test solution with diluent and perform the bacterial count test according to Hygiene Test Method; the limit is not more than  $1 \times 10^2$  cfu/g.

## Mold Count

Take 5g of this solution, make 50mL test solution with diluent and perform the mold count test according to Hygiene Test Method; the limit is not more than  $1 \times 10^2$  cfu/g.

## Coli form

Take 1mL of the solution which prepare the bacterial count test, and perform the coli form test according to Hygiene Test Method; Negative / Not observe any colony.

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	: ORYZAFERULIX
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

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