Oryza

ORYZA OIL & FAT CHEMICAL CO., LTD.

# PASSIONFLOWER EXTRACT

## Improving Life Rhythm, Biological Clock and Quality of Sleep

- **PASSIONFLOWER EXTRACT-P**
  **（Powder, Food Grade）**
- **PASSIONFLOWER EXTRACT-WSP**
  **（Water-soluble Powder, Food Grade）**
- **PASSIONFLOWER EXTRACT-PC**
  **（Powder, Cosmetic Grade）**
- **PASSIONFLOWER-WSPC**
  **（Water-soluble Powder, Cosmetic Grade）**

オリザ油化株式会社

**Ver. 1.0NS**

# PASSIONFLOWER EXTRACT

## Improving Life Rhythm, Biological Clock and Quality of Sleep

## 1. Introduction

Passionflower (*Passiflora incarnata*) is a type of over 520 types of *Passiflora* family plants. As its flower has a similar shape to a clock, this perennial vine plant is called *Tokeiso* (*Chabotokeiso*) ("*tokei*" means clock in Japanese) in Japan (Fig. 1). Passionflower symbolizes "holy love" in the language of flowers. Its place of origin is tropical and subtropical areas of North, South and Central America. The passionflower was used by indigenous people as a sedative agent. It was brought to Europe by Spanish people and became a popular sedative agent effective for treating anxiety and insomnia. Currently, it is approved as a medicine (medicinal herb) in Egypt, France, Germany, England and the United States.[1)] In Japan, the fruit, stem, leaves and flowers of passionflower are classified into the groups of non-pharmaceutical plants (not regarded as medicine) in the Food and Drug Classification List as far as their pharmaceutical effect is not claimed.

Fig.1 Passionflower *(Passiflora incarnata*)

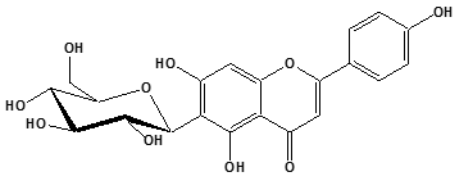
Although many clinical trials of passionflower on anxiety and relieve insomnia have been carried out, the action mechanism has not been well understood[1)] . Oryza Oil & Fat Chemical Co., Ltd. studied the effect of passionflower on the human biological clock (circadian rhythm; life rhythm). As a result, we found that passionflower extract and its components have an effect to enhance the expression of clock genes (genes controlling the circadian rhythm). Passionflower extract can be used in the foods for improving the life rhythm and quality of sleep, because it regulates our biological clock. Passionflower extract is a highly effective product to help people who care for a healthy condition both day and night.

1) Miroddi M., et al. *Passiflora incarnata* L.: ethnopharmacology, clinical application, safety and evaluation of clinical trials. *J. Ethnopharmacol.* 150, 791-804 (2013).

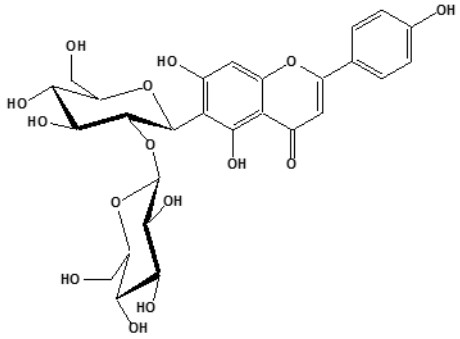
## 2. Components of Passionflower

It has been reported that passionflower contains several flavonoid glycosides. Oryza Oil & Fat Chemical purified the components of passionflower and identified its structure with Kyoto Pharmaceutical University. The chemical structure was determined by NMR spectra (Fig. 2).

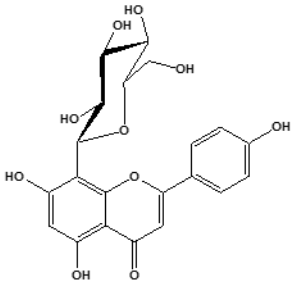
**< Flavonoids>**



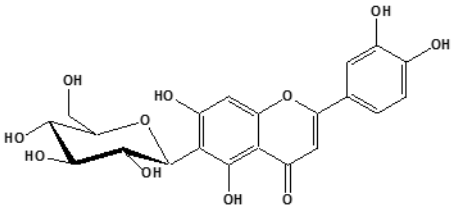
Isovitexin



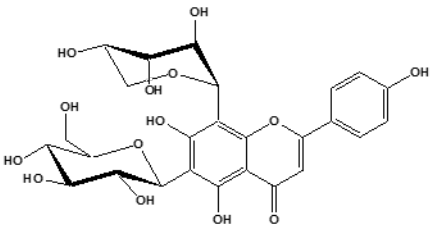
Isovitexin-*O*-gulcoside



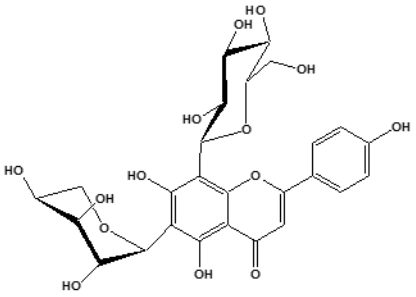
Vitexin



Homoorientin



Schaftoside



Isoschaftoside

Fig.2 Components of passionflower

# 3. Effect of Passionflower Extract on Circadian Rhythm

## （1） Circadian rhythm (biological clock) and clock genes

The circadian rhythm, also called biological clock, is a physiological phenomenon that changes in approximately 24 hour cycle (about one day). Almost all organisms have this rhythm, which controls physiological activities including sleeping, awakening, digestion, absorption, metabolism, hormonal secretion and the regulation of blood pressure and body temperature. The disruption of circadian rhythm is associated with a variety of diseases including the impairment of endocrine function, metabolic homeostasis and autonomic nerve system. It is believed that abnormal circadian rhythm causes jet lag, sleeping disorder and lifestyle-related diseases such as obesity, high blood pressure, diabetes and mental illness. Circadian rhythm is affected not just by external factors (ex. light, temperature, diet and stress) but by internal factors such as aging. The aging process leads to major alterations in rhythms of the circadian clock. Elderly people have a faster circadian rhythm because the amplitude is smaller than younger people[2)]. As a result, their physical condition does not alter during the day or at night and then their life rhythm (biological clock) is disrupted. Genes that regulates the circadian rhythm are called “clock genes”. Per and Cry, of which expression increases during daytime (active period) and Bmal and Clock, of which expression increases at night (rest period) are regarded as the main indicator to assess the pattern of circadian rhythm (Fig. 3).

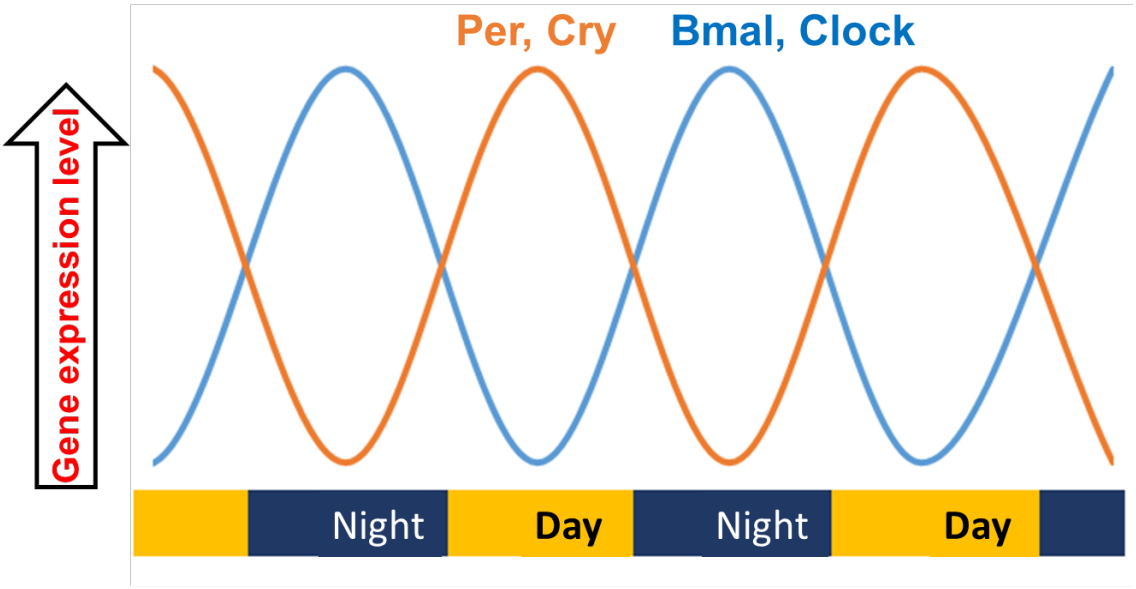



Fig.3 Circadian rhythm and clock genes

2） Froy O. Circadian rhythms, aging, and life span in mammals. *Physiology*, 26, 225-235 (2011).

## （2）Effect of Passionflower Extract and Its Components on the Clock Genes Expression in Fibroblasts

Passionflower extract (PFE; 100 μg/mL) was added to the culture medium of mouse fibroblasts (NIH3T3) entrained the circadian rhythm. For measuring the expression levels of clock genes mRNA, the cells were harvested at different time points (0, 4, 8, 12, 16, 20 and 24 hours) after PFE treatment. As shown in Fig.4, the expression levels of Per2 mRNA were most increased at 20 hr after PFE treatment. Cry1 mRNA levels also significantly increased at 24 hr after treatment. The expression of clock genes significantly increased in the PFE group as compared to the control group (Fig. 4).

PFE and five separated components (isovitexin, isovitexin-2'-*O*-glucoside, schaftoside, isoschaftoside, homoorientin) were added at 10 or 30 μg/mL according to the same method as above. The expression levels of clock genes mRNA were measured at 20 hr after treatment because Per2 expression peaked at this time (Fig.4). As a result, PFE significantly increased Per2 mRNA expression at the concentration of 30 μg/mL. Moreover, isovitexin-2'-*O*-glucoside (10 μg/mL), isoschaftoside (30 μg/mL) and homoorientin (10 and 30 μg/mL) also significantly increased the Per2 mRNA expression (Fig. 5). These results indicate that three components of passionflower are related to the activity of PFE for increase the expression of Per2 mRNA.

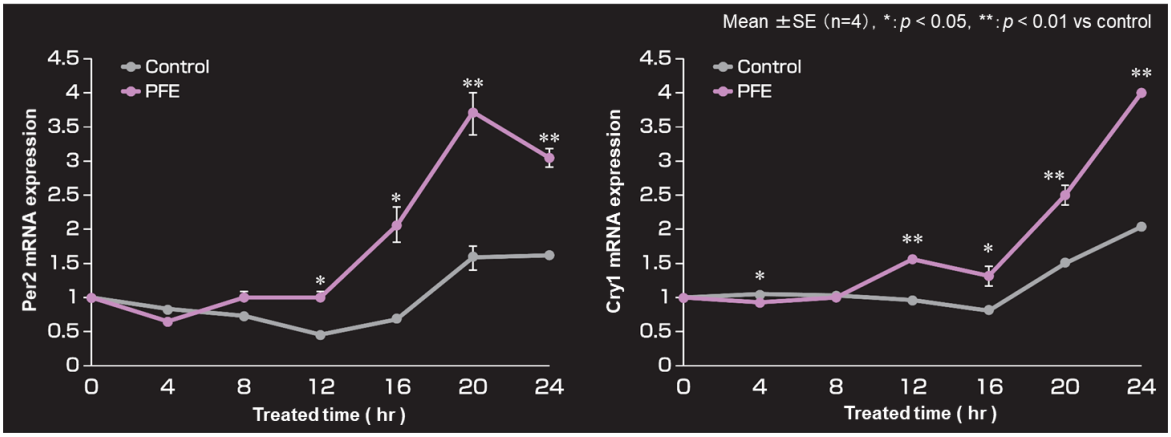



Fig.4 Effect of passionflower extract (PFE) on the mRNA expression of Per2 and Cry1 in fibroblasts.

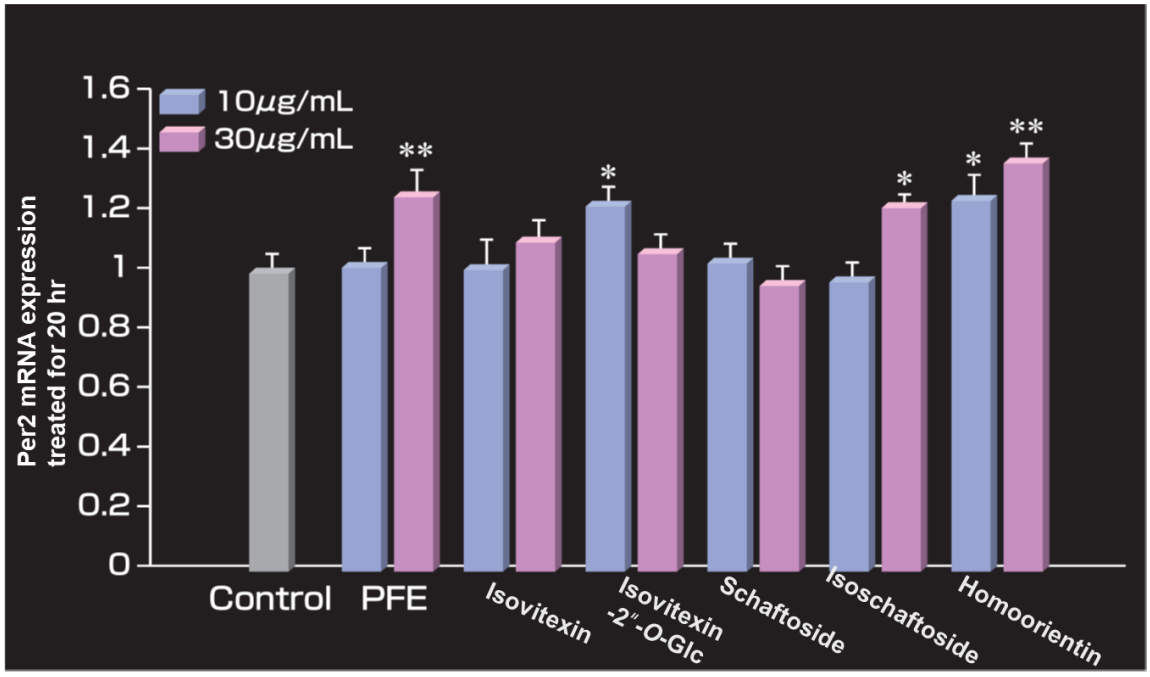



Fig. 5 Effect of passionflower extract (PFE) and its components on the expression of Per2 mRNA
Mean±SE（n=4），＊：$p < 0.05$，＊＊：$p < 0.01$ vs control

## （3-a）Effect of Passionflower Extract on Sleeping Behavior and Clock Genes Expression in Mice

In the previous chapter, we showed that PFE has the activity to increase the clock genes expression in cultured cells. As next step, we evaluated its effect on sleeping behavior and clock genes expression in mice. PFE was administered to the mice in the PFE group by 100 mg/kg and water was administrated to the mice in other two groups for 15 days. Pentobarbital sleep test was conducted on the 15th day as shown in Fig. 6. Pentobarbital is a sedative hypnotic. Muscimol, reagent to relax by working on GABA receptors, was administrated into the abdominal cavity of the mice in the Muscimol group 15 minutes before the administration of Pentobarbital. Muscimol is often used in Pentobarbital sleeping tests. It is a positive control which is known to accelerate the sleep-onset time and increases the sleeping time.

The “sleep latency” is the time that it took for the mice to fall asleep after the administration of pentobarbital. The “sleeping time” is the time between when the mice fall asleep and wake up. As shown in Fig.7, the sleep latency was reduced and sleeping time was increased in the PFE and Muscimol groups as compared to the control group. Finally, the mRNA expression of clock genes in the liver was measured every 6 hr in each group. **Because mice are nocturnal, active phase of mice starts at 8:00 PM when it is dark.** As a result, the expression levels of Per2 and Cry1 in the active phase significantly increased in the PFE group (Fig. 8). These results suggest that **PFE has the activity to help fall asleep and increase the sleeping time**. **It can be concluded that PFE increase the expression of clock genes Per2 and Cryl1 both *in vitro* and *in vivo***.

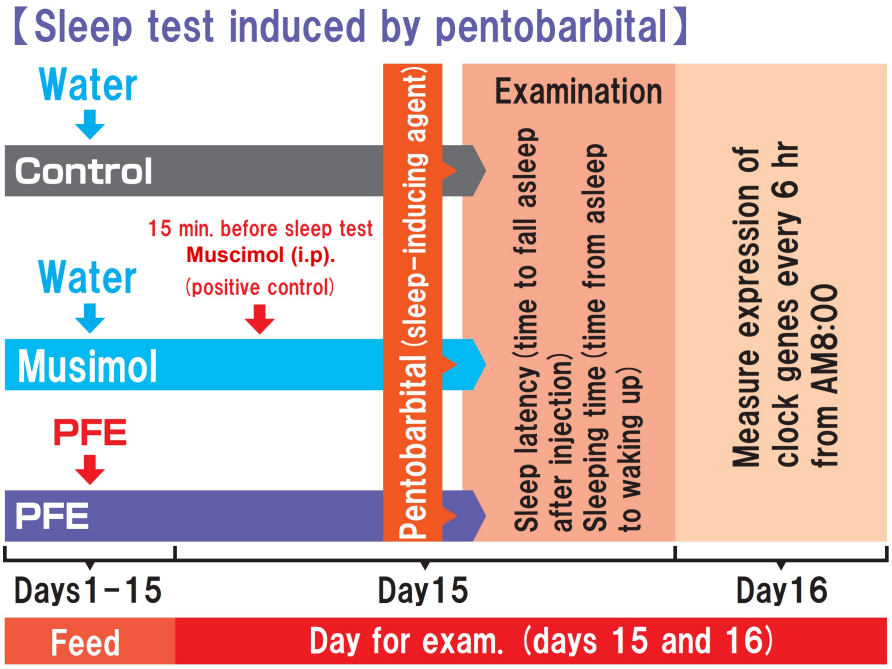



Fig.6 Sleep test induced by pentobarbital

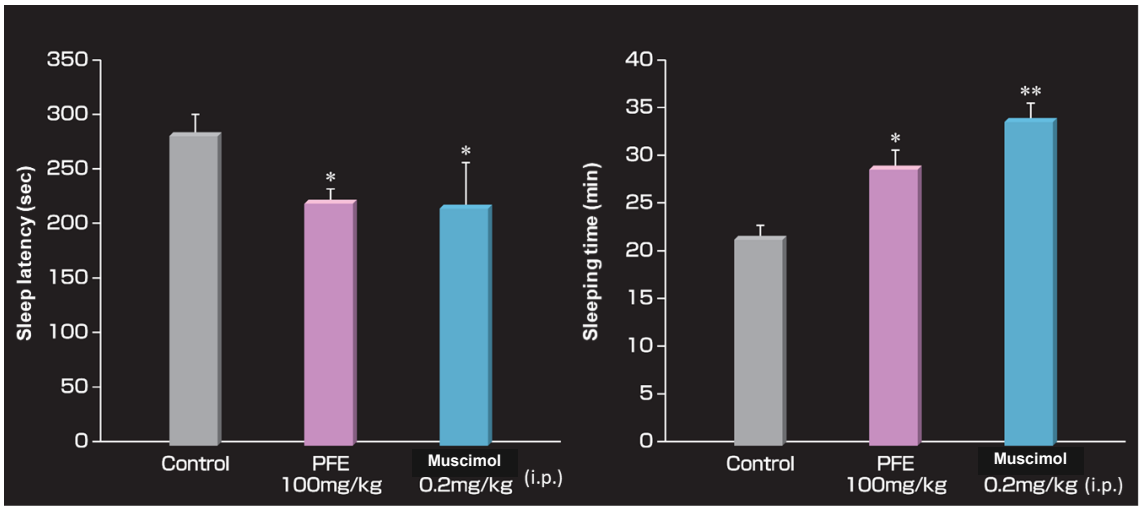



Fig.7 Effect of passionflower extract (PFE) and muscimol on sleep latency and sleeping time in mice.

Mean±SE (n=10～16), * : $p < 0.05$, ** : $p < 0.01$ vs control

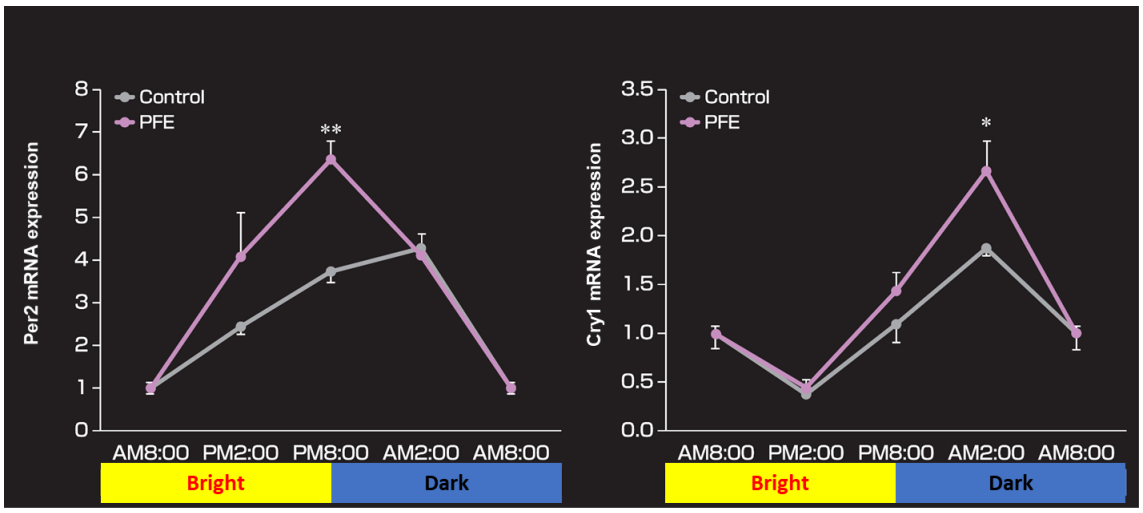



Fig. 8 Effect of passionflower extract (PFE) on the expression of Per2 and Cry1 mRNA Mean±SE (n=4), * : $p < 0.05$, ** : $p < 0.01$ vs control

## （3-b）Effect of Passionflower Extract on the Pattern of Corticosterone Secretion in Mice

Corticosterone is a steroid hormone that is believed to play a crucial role in both sleep and waking states. It is known that corticosterone secretion varies throughout the day. Since rats are nocturnal, the corticosterone secretion is lower in the morning (rest phase for rats) and higher at night (active period for rats) [3]. Thus, corticosterone level also follows a circadian rhythm. To evaluate the effect of PFE on corticosterone secretion, we measured the amount of corticosterone in mouse serum every 6 hr. As shown in Fig.9, the corticosterone level in the control group peaked at 8:00 PM (the start of active period for mice). The amount of corticosterone significantly increased in the PFE group as compared to the control group. This result shows that PFE regulates not only the rhythm of clock genes expression but also the rhythm of the corticosterone secretion.

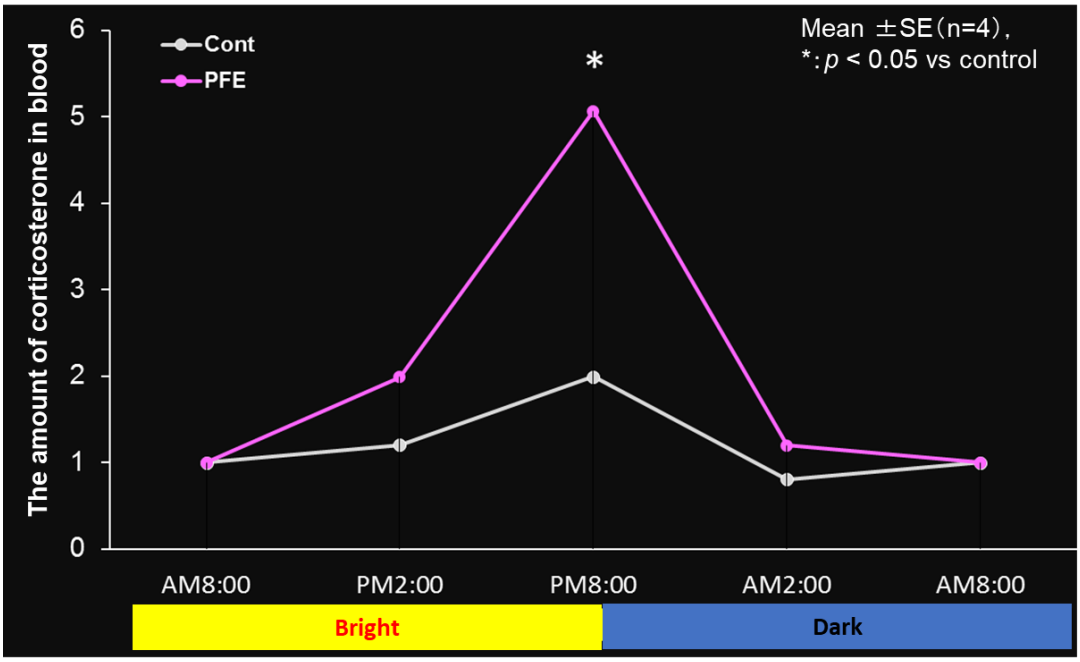



Fig. 9　Effect of passionflower extract (PFE) on the secretion of blood corticosterone in mice
Mean±SE（n=4），＊：$p < 0.05$ vs control

3）Vazquez-Palacios, G., et al. Further definition of the effect of corticosterone on the sleep–wake pattern in the male rat. *Pharmacol. Biochem. Behav.* 70, 305-310 (2001).

## （3-c）Effect of Passionflower Extract on the Expression of Clock Genes in Mouse Brain

We measured the mRNA expression of clock genes in mouse brain every 6 hr. As shown in Fig. 10, the sharpness of the maximum and the minimum expression level of Bmal1 and Clock mRNA were significantly increased compared with control group. These results imply that PFE increased the amplitude of Bmal1 and Clock expression in mouse brain and improves the circadian rhythm.

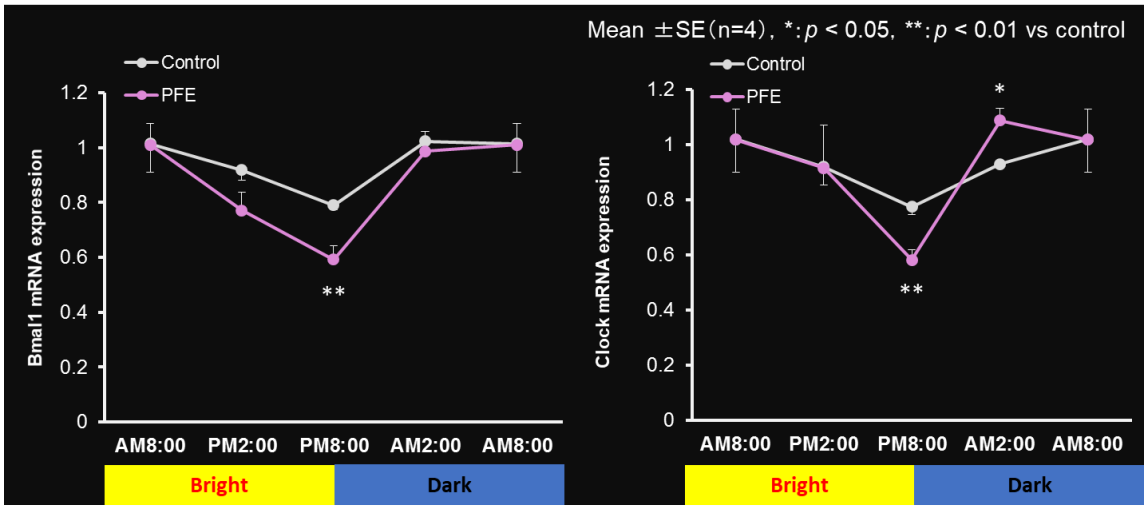



Fig. 10　Effect of passionflower extract (PFE) on the expression of Bmal1 and Clock mRNA　Mean±SE（n=4），＊：$p < 0.05$，＊＊：$p < 0.01$ vs control

## （4） Monitoring Test

A double-blind crossover test was carried out on 16 volunteer Oryza employees (11 males, 5 females). Subjects ingested Passionflower extract-P (PFE, for specifications of Passionflower extract-P, see page 18) by 200 mg/day or placebo (Maltodextrin) for two weeks. The Athens Insomnia Scale was used to evaluate the effect of PFE on quality of sleep in human. The Athens Insomnia Scale was established by Worldwide Project on Sleep and Health )World Health Organization; WHO) and is a universal method to assess insomnia symptoms. Higher scores indicate the possibility of insomnia (sleeping disorders) (Table 1). In other words, when the changes in the scores before and after the ingestion are compared, lower values indicate more improvement of sleep disturbance. In this test, we evaluated that the changes in total scores and in the score on “mood”, “activities” and “sleepiness” during daytime before and after ingestion of the extract. As shown in Fig.10 and 11, the ingestion of Passionflower extract-P showed the tendency of improvement for all of these items as compared to that of placebo. According to our results of cell experiments, mouse tests and clinical trials, PFE is expected to increase the expression of clock genes (Per2, Cry1) and adjust the physical condition both day and night by regulating the biological clock. For this reason, it is considered that the ingestion of this extract improved the “mood”, “activities” and “sleepiness” scores during daytime in the monitoring test on humans (Table 1). In other words, **PFE have the activity to improve the life rhythm and quality of sleep** through the new mechanism regulating biological clock.

Table. 1　The Athens Insomnia Scale

| ATHENS INSOMNIA SCALE | |
|---|---|
| 1. SLEEP INDUCTION (time it takes you to fall asleep after turning-off the lights)<br>0 No problem<br>1 Slightly delayed<br>2 Markedly delayed<br>3 Very delayed or did not sleep at all | 5. OVERALL QUALITY OF SLEEP<br>0 Satisfactory<br>1 Slightly unsatisfactory<br>2 Markedly unsatisfactory<br>3 Very unsatisfactory or did not sleep at all |
| 2. AWAKENINGS DURING THE NIGHT<br>0 No problem<br>1 Minor problem<br>2 Considerable problem<br>3 Serious problem or did not sleep at all | 6. SENSE OF WELL-BEING DURING THE DAY<br>0 Normal<br>1 Slightly decreased<br>2 Markedly decreased<br>3 Very decreased |
| 3. FINAL AWAKENING EARLIER THAN DESIRED<br>0 Not earlier<br>1 A little earlier<br>2 Markedly earlier<br>3 Much earlier or did not sleep at all | 7. FUNCTIONING (PHYSICAL AND MENTAL) DURING THE DAY<br>0 Normal<br>1 Slightly decreased<br>2 Markedly decreased<br>3 Very decreased |
| 4. TOTAL SLEEP DURATION<br>0 Sufficient<br>1 Slightly insufficient<br>2 Markedly insufficient<br>3 Very insufficient or did not aleep at all | 8. SLEEPINESS DURING THE DAY<br>0 None<br>1 Mild<br>2 Considerble<br>3 Intense |

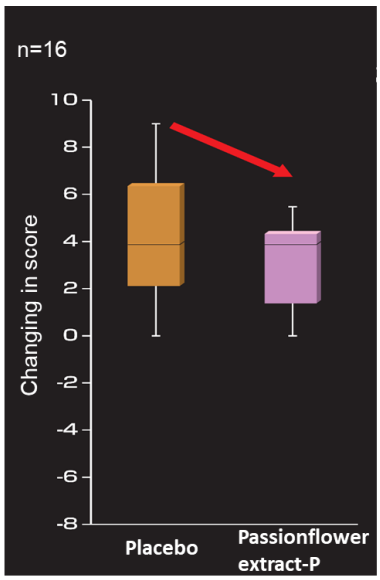



Fig. 10 Change in total score of The Athens Insomnia Scale
Box-and-whisker diagram displays the amount of change of the 10, 25, 50, 75, 90 percentile score

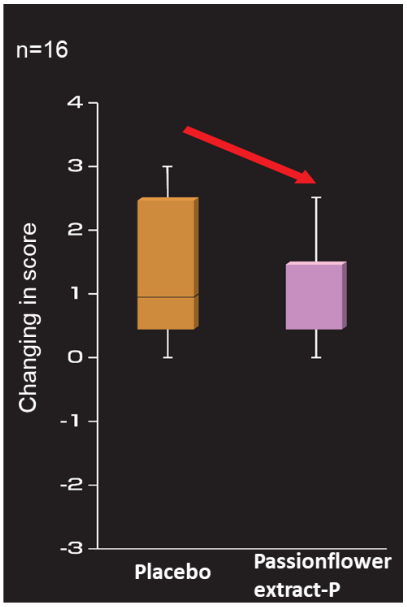



Fig.11 Change in the score at daytime of The Athens Insomnia Scale
Box-and-whisker diagram displays the amount of change of the 10, 25, 50, 75, 90 percentile score

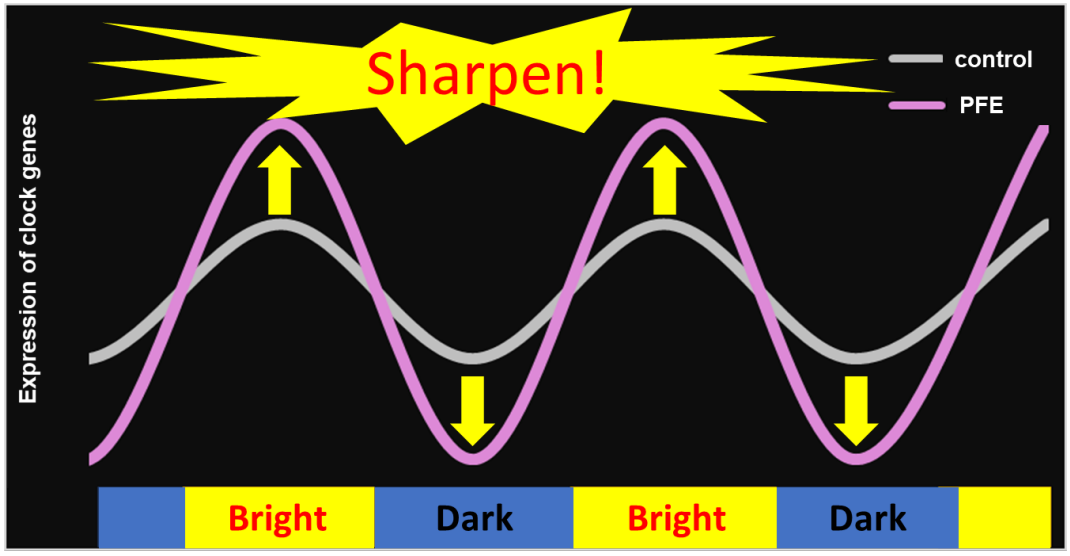



Fig.12 The action of passionflower extract (PFE) on circadian rhythm

# 4. Antioxidant Activity of Passionflower Extract

To confirm the antioxidant activity of PFE (100 μg/mL), we added it to the culture medium of mouse fibroblasts (NIH3T3) entrained the circadian rhythm. The gene expression levels of antioxidation-related enzymes (GPx1, SOD1) were measured. The mRNA expression was measured at 16 hr after the treatment because this time point was considered to be the rest period (night time) according to the results in Fig. 4. As a result, the mRNA expression of GPx1 and SOD1 significantly increased in PFE group as compared to that of control group (Fig. 13). These results indicated that PFE have an effect to increase the mRNA expression of antioxidation-related enzymes during night time and to protect the skin (especially fibroblasts) from reactive oxygen species which generated by UV irradiation and external stress stimulus during daytime.

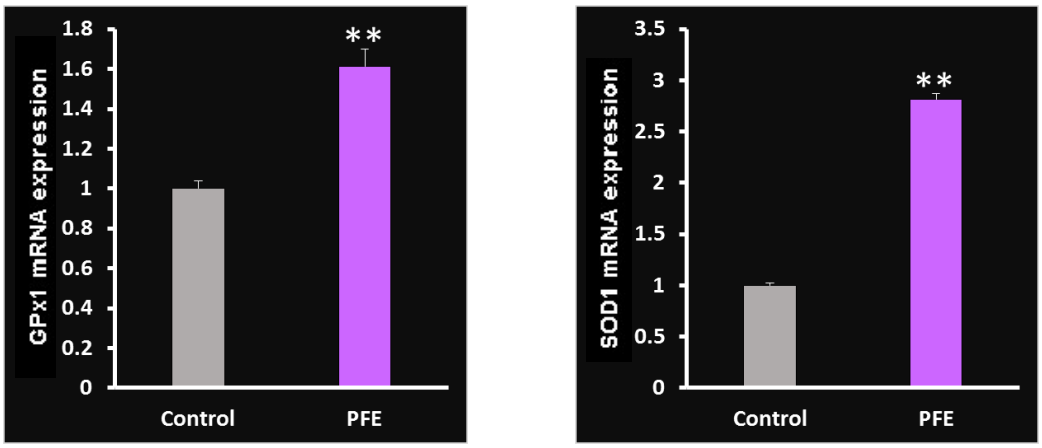



Fig. 13 Effect of Passionflower extract (PFE) on the expression of GPx1 and SOD1 mRNA Mean±SE（n=4）, ** : $p < 0.01$ vs control

# 5. Product Stability of Passionflower Extract

## (1) Heat stability

The heat stability of Passionflower Extract-P was examined by heating at 120°C continuously for 1 hour. As shown in Fig. 14, total flavonoid content was not reduced after heating for 1 hour. Therefore, Passionflower Extract-P is highly stable upon heating at normal food processing temperature.

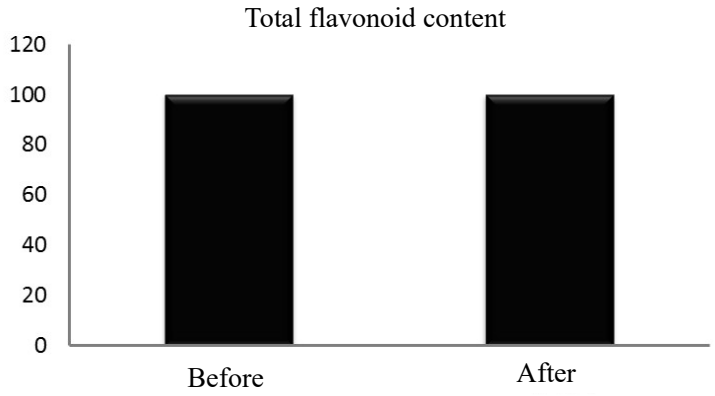



Fig. 14 The heat stability of Passionflower Extract

## (2) pH stability

The pH stability of Passionflower Extract-WSP was examined. It was stored at different pH value at room temperature for a week. No alteration was observed neither in the color of extract nor in the polyphenol content.

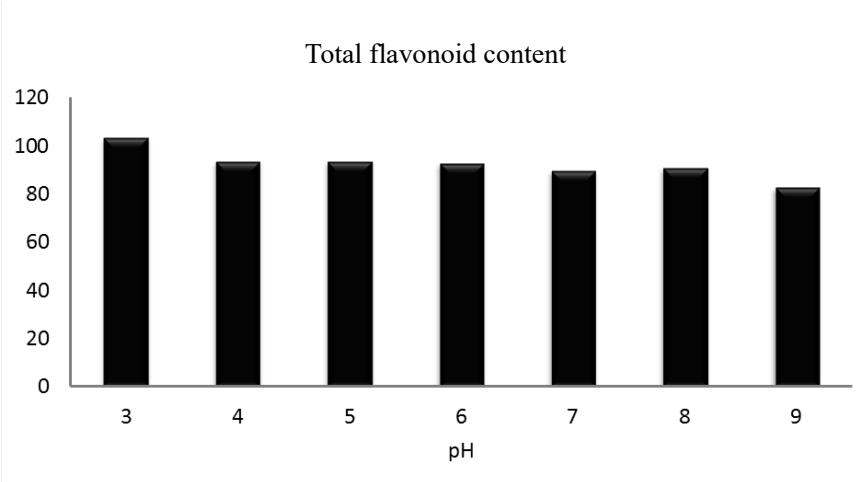



Fig.15 The pH stability of Passionflower Extract

# 6. Nutrition Profiles

| Analyzed item (/100g) | P | WSP | Method |
|---|---|---|---|
| Water (g) | 4.6 | 2.9 | Heating drying method under normal pressure |
| Protein (g) | 9.7 | 5.5 | Kjeldahl method, nitrogen protein conversion factor: 6.25 |
| Fat (g) | 0.9 | 0.4 | Acid decomposition method |
| Ash (g) | 8.5 | 5.4 | Direct incineration method |
| Carbohydrate (g)<br>－Sugar (g)<br>－Fiber (g) | 76.3<br>75.7<br>0.6 | 85.8<br>84.7<br>1.1 | Refer note 1<br>Prosky's method |
| Energy (kcal) | 351 | 367 | Refer note 2 |
| Sodium (mg) | 134 | 87.7 | Atomic absorption spectrophotometory |
| Sodium chloride equivalent (g) | 0.34 | 0.22 | Refer note 3 |

The nutritional information of Passionflower Extract was analyzed according to the standard in nutrition labeling (March 30, 2015; No 139 Eishin)
Note 1: Calculation: 100-(water + protein + fat + ash)
Note 2: Energy conversion factor: Protein 4, fat 9, sugar 4, dietary fiber 2
Note 3: In terms of sodium
Test trustee: SUNATECH / Date of analysis: Aug 22, 2016
Test No.:160804527-001-01

# 7. Safety Profile

## （1） Residual Agricultural Chemicals

Passionflower extract was screened and analyzed for residual agricultural chemicals (532 items) stipulated under the Food Sanitation Act and Pesticides Control Act, presence of the test items was lower than the allowed limits.

Test Trustee: Masis Co., Ltd.; Center for Food Safety Evaluation and Analysis
Date: Aug 24, 2016
Report No. 106731

### （2） Acute Toxicity（$LD_{50}$）

Acute Toxicity test was conducted according to the Guidelines for Single-Dose Toxicity Tests for Pharmaceutical Products where Passionflower Extract 2000 mg/kg was orally given to fasted ICR mice (6 weeks old) for 14 days. No abnormalities and fatal event observed at 2000 mg/kg. No abnormalities were observed under macroscopic examination upon autopsy. Thus, LD50 of Passionflower Extract is deduced to be >2000 mg/kg.

## 8. Recommended Dosage

In accordance to the result of human clinical trials, the recommended dosage of Passionflower Extract-P is 200 mg/day and Passionflower Extract-WSP is 600 mg/day.

## 9. Application

| | Application | Claims | Examples |
|---|---|---|---|
| Food | Nutritional Supplement, Beauty Food | -Improving Life rhythm, -Improving Quality of Sleep, -Skin beauty effect | Beverages, Hard and soft capsules, tablets, candies, chewing gums, gummies, cookies, chocolates, wafers, jellies etc. |
| Cosmetic | Beauty | | Toner, lotions, pack, body gel etc. |

## 10. Packing

Passionflower Extract-P（PC），-WSP（WSPC）

1 kg, 5 kg　　Interior packing:：Aluminium bag

Exterior packing：Cardboard box

## 11. Storage

Store in a dry, ventilated location. Keep away from high temperature and sun light, store in the closed containers.

# 12. Expression

**<Food>**

**Passionflower Extract-P**
Passionflower Extract, Maltodextrin, Silica

**Passionflower Extract-WSP**
Maltodextrin, Passionflower Extract

**<Cosmetics>**

**Passionflower Extract-PC**
Passionflower Extract, Maltodextrin, Silica
INCI name：PASSIFLORA INCARNATA EXTRACT (AND) MALTODEXTRIN (AND) SILICA

**Passionflower Extract-WSPC**
Maltodextrin, Passionflower Extract
INCI name：MALTODEXTRIN (AND) PASSIFLORA INCARNATA EXTRACT

# 13. Restrictions on use

**<Food>**

**Passionflower Extract-P，-WSP**

Pregnant women should not take passionflower because passionflower contains chemicals that can cause the uterus to contract. Furthermore, the safety of passionflower during breastfeeding remained unclear. Pregnant women should not use passionflower due to the lack of safety assurance.

Reference:
"Natural Medicines Comprehensive Database -Unbiased, Scientific Clinical Information on Complementary, Alternative, and Integrative Therapies
http://naturaldatabase.therapeuticresearch.com/home.aspx?cs=&s=ND
"EUROPEAN MEDICINES AGENCY -SCIENCE MEDICINES HEALTH
http://www.ema.europa.eu/ema/

# PRODUCT STANDARD

# PASSIONFLOWER EXTRACT-P (FOOD)

This product is extracted with aqueous ethanol from the stems, leaves and flowers of passionflower (*Passiflora incarnata* L.). It contains a minimum of 3.0% total flavonoids.

| | | |
|---|---|---|
| **Appearance** | Pale yellowish brown to yellowish brown powder with slightly characteristic odor. | |
| **Total flavonoids** | Min. 3.0 % | (HPLC) |
| **Loss on Drying** | Max. 10.0 % | (Analysis for Hygienic Chemists, 1 g, 105ºC, 2 hr) |
| **Purity Test** | | |
| **(1) Heavy Metals (as Pb)** | Max. 20 ppm | (Sodium Sulfide Colorimetric Method) |
| **(2) Arsenic (as $As_2O_3$)** | Max. 2 ppm | (Standard Methods of Analysis in Food Safety Regulation, The Third Method, Apparatus B) |
| **Standard Plate Counts** | Max. $1\times10^3$ cfu/g | (Analysis for Hygienic Chemists) |
| **Moulds and Yeasts** | Max. $1\times10^2$ cfu/g | (Analysis for Hygienic Chemists) |
| **Coliforms** | Negative | (Analysis for Hygienic Chemists) |

**Composition**

| Ingredient | Content |
|---|---|
| Passionflower extract | 60% |
| Maltodextrin | 38% |
| Silica | 2% |
| Total | 100% |

| | |
|---|---|
| **Expiry date** | 2 years from date of manufacturing. |
| **Storage** | Store in a dry, ventilated location. Keep away from high temperature and sun light, store at room temperature in an original closed container. |

# PRODUCT STANDARD

# PASSIONFLOWER EXTRACT-WSP (FOOD)

This product is extracted with water from the stems, leaves and flowers of passionflower (*Passiflora incarnata* L.). It contains a minimum of 1.0% total flavonoids.

| | | |
|---|---|---|
| **Appearance** | Pale yellow to pale brown powder with slightly characteristic odor. | |
| **Total flavonoids** | Min. 1.0 % | (HPLC) |
| **Loss on Drying** | Max. 10.0 % | (Analysis for Hygienic Chemists, 1 g, 105ºC, 2 hr) |
| **Purity Test** | | |
| **(1) Heavy Metals (as Pb)** | Max. 20 ppm | (Sodium Sulfide Colorimetric Method) |
| **(2) Arsenic (as $As_2O_3$)** | Max. 2 ppm | (Standard Methods of Analysis in Food Safety Regulation, The Third Method, Apparatus B) |
| **Standard Plate Counts** | Max. $1\times10^3$ cfu/g | (Analysis for Hygienic Chemists) |
| **Moulds and Yeasts** | Max. $1\times10^2$ cfu/g | (Analysis for Hygienic Chemists) |
| **Coliforms** | Negative | (Analysis for Hygienic Chemists) |

**Composition**

| Ingredient | Content |
|---|---|
| Maltodextrin | 67% |
| Passionflower extract | 33% |
| Total | 100% |

| | |
|---|---|
| **Expiry date** | 2 years from date of manufacturing. |
| **Storage** | Store in a dry, ventilated location. Keep away from high temperature and sun light, store at room tempe rature in an original closed container. |

# PRODUCT STANDARD

# PASSIONFLOWER EXTRACT-PC(COSMETIC)

This product is extracted with aqueous ethanol from the stems, leaves and flowers of passionflower (*Passiflora incarnata* L.). It contains a minimum of 3.0% total flavonoids.

| | | |
|---|---|---|
| **Appearance** | Pale yellowish brown to yellowish brown powder with slightly characteristic odor. | |
| **Total flavonoids** | Min. 3.0 % | (HPLC) |
| **Loss on Drying** | Max. 10.0 % | (1 g, 105ºC, 2 hr) |
| **Purity Test** | | |
| **(1) Heavy Metals (as Pb)** | Max. 20 ppm | (The Second Method of The Japanese Standards of Quasi-Drug Ingredients) |
| **(2) Arsenic (as $As_2O_3$)** | Max. 2 ppm | (The Third Method of The Japanese Standards of Quasi-Drug Ingredients) |
| **Standard Plate Counts** | Max. $1\times10^2$ cfu/g | (Analysis for Hygienic Chemists) |
| **Moulds and Yeasts** | Max. $1\times10^2$ cfu/g | (Analysis for Hygienic Chemists) |
| **Coliforms** | Negative | (Analysis for Hygienic Chemists) |

**Composition**

| Ingredient | Content |
|---|---|
| Passiflora Incarnata Extract | 60% |
| Maltodextrin | 38% |
| Silica | 2% |
| Total | 100% |

| | |
|---|---|
| **Expiry date** | 2 years from date of manufacturing. |
| **Storage** | Store in a dry, ventilated location. Keep away from high temperature and sun light, store at room tempe rature in an original closed container. |

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 STANDARD

## PASSIONFLOWER EXTRACT-WSPC (COSMETIC)

This product is extracted with water from the stems, leaves and flowers of passionflower (*Passiflora incarnata* L.). It contains a minimum of 1.0% total flavonoids.

| | | |
|---|---|---|
| **Appearance** | Pale yellow to pale brown powder with slightly characteristic odor. | |
| **Total flavonoids** | Min. 1.0 % | (HPLC) |
| **Loss on Drying** | Max. 10.0 % | (1 g, 105ºC, 2 hr) |
| **Purity Test** | | |
| **(1) Heavy Metals (as Pb)** | Max. 20 ppm | (The Second Method of The Japanese Standards of Quasi-Drug Ingredients) |
| **(2) Arsenic (as $As_2O_3$)** | Max. 2 ppm | (The Third Method of The Japanese Standards of Quasi-Drug Ingredients) |
| **Standard Plate Counts** | Max. $1\times10^2$ cfu/g | (Analysis for Hygienic Chemists) |
| **Moulds and Yeasts** | Max. $1\times10^2$ cfu/g | (Analysis for Hygienic Chemists) |
| **Coliforms** | Negative | (Analysis for Hygienic Chemists) |

**Composition**

| Ingredient | Content |
|---|---|
| Maltodextrin | 67% |
| Passiflora Incarnata Extract | 33% |
| Total | 100% |

| | |
|---|---|
| **Expiry date** | 2 years from date of manufacturing. |
| **Storage** | Store in a dry, ventilated location. Keep away from high temperature and sun light, store at room tempera ture in an original closed container. |

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.

**ORYZA OIL & FAT CHEMICAL CO., LTD.** striving for the development of the new functional food materials to promote health and general well-being.

**From product planning to OEM** - For any additional information or assistance, please contact：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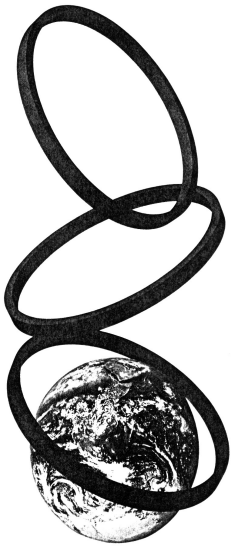

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