

Product Specification : Cosmetic Product 002

(ผลิตภัณฑ์เครื่องสำอาง)

Name : **Hair Lotion Spray**
(แฮร์โลชั่นสเปรย์)

Thai FDA Registration No. : 50-1-5901303

Active Compositions : Containing natural products of cocktails from extracts of Thai medicinal plants including Sorghum/ ข้าวจ้าว (*Sorghum bicolor*), Soy Bean/ ถั่วเหลือง (*Glycine max* (L.) Merrill), Pamelol/ ส้มโอ (*Citrus maxima* (Burm.) Merrill), Butterfly Pea/ อัญชัน (*Clitoria ternatea* L.) and Tamarind/ มะขาม (*Tamarindus indica* L.) encapsulated in nanovesicles

Characteristics :

- Physical appearance : Dark brownish clear solution
- pH : 5
- Odor : Specific herbal odor

- Particle size and zeta potential : Particle size in nanosize range of 19.17 ± 1.01 nm with the zeta potential value of (-) 4.67 ± 0.33 mV

Standardization : Phytochemicals including linoleic acid (1.84 mg/g), quercetin (8.22 μ g/g) and anthocyanin (8.00 μ g/g) are used as markers for HPLC fingerprints as the control of standardization and product uniformity

Biological activities :

- Antioxidation activity by scavenging of DPPH free radical and inhibiting of lipid peroxidation at the SC_{50} and IPC_{50} values of more than 1000 mg/ml
- Anti-inflammation activity by the inhibition of denaturation by heat of albumin from egg white with the IC_{50} value of 10.61 mg/ml in comparing to the standard inflammatory drug, diclofenac which gave the IC_{50} value of 2.38 mg/ml
- Stimulation of melanin (melanogenesis) by stimulating melanin pigment production and stimulation of the activity of tyrosinase in melanoma cells (B16F10) at the relative ratio

of melanin content and relative ratio of tyrosinase activity at 115.66 ± 16.11 and $117.89 \pm 12.13\%$ of 1.08 and 0.92 folds of theophylline, respectively

Animal study :

- Increase numbers of hair on aged black mice more than the negative control and the dutasteride groups after 6 weeks of topical application
- In histopathology observation, increase of hair follicle numbers of the aged black mice more than the negative control and the dutasteride groups after 3 and 6 weeks of topical application
- More numbers of growth and density of hair on rabbit's back in comparing to the negative control and the group applied with 5% minoxidil
- No irritation of the product when applied on the shaved rabbit's back

Clinical Performance :

- When tested in 15 human volunteers for 8 weeks in comparing to 1% minoxidil, most volunteers give an increased number of hair with decreasing of falling hair more than when applied with 1% minoxidil

Microbial Contamination : None

Safety Evaluation : No skin irritation in human volunteers

Stability : Physical and chemical stability by the freeze-thaw process (45 and 4 °C) of 6 cycles using linoleic acid and quercetin as markers indicating of linoleic acid and quercetin remaining of about 95 and 74% respectively after the test

Shelf life at 30 °C : 5 years

Indication : Spray on the hair, hair base or scalp where is canities and hair loss or less hair with 1 minute massage every day, after shampooing in the evening without rinsing off and shampooing in the next morning. Use continuously for 1-2 months.

Packaging and Storage : 50 ml in a bottle with sprayer/ keep in dry and cool place protected from light

Precaution : For external use only, avoid inhalation and get into eyes. If there is any undesirable effect, wash out immediately and stop using.