
Specification : Pain Patch 011 (Manose PR-0025)

(Application : For anti-inflammation and pain relief)

1. Name : Pain Patch 011
2. Active Compositions : Methyl salicylate, *Zingiber cassumunar* Root Oil, *Alpinia galanga* Root Oil, Menthol, *Cinnamomum camphora* and others
3. FDA Registration No. : In the process of registration as cosmetics to Thai FDA
4. Characteristics
 - Physical appearance : Opaque yellowish flexible patch
 - pH : 5.71
 - Odor : Herbal odor
5. Standardization : HPLC fingerprint using gallic acid as a marker
6. Biological activities : Anti-inflammatory activity in rats by the ethyl phenylpropionate-induced ear edema method with the highest % edema inhibition of $73.68 \pm 6.20\%$ after 60 minutes, while the standard anti-inflammatory product (1% diclofenac sodium gel) gave the maximum inhibitory effect on ear swelling with the % edema inhibition of $91.23 \pm 26.32\%$ after 60 minutes. The Pain Patch 011 exhibited an anti-inflammatory effect of 0.81 time or 81% of the standard anti-inflammatory pharmaceutical product.
7. Clinical Performance : -
8. Microbial Contamination : No pathogenic microorganism contamination and the amounts of the aerobic bacteria, yeast and fungi are less than 1,000 cfu/g which is in an acceptable range of the Thai FDA, Ministry of Public Health
9. Safety Evaluation : No skin irritation in human volunteers

- 10. **Stability** : Physically stable by the heating-cooling process of 6 cycles
- 11. **Shelf life at 25 °C** : 2-3 years
- 12. **Indication and use** : Fix the patch on the needed skin for pain relief and anti-inflammation
- 13. **Packaging and Storage** : The patch size of 5x7 cm, packed in an opaque plastic bag, keep in dry, cool place and protected from light
- 14. **Precaution** : If there is any undesirable effect such as itching, remove the patch and rinse the skin with clean water
- 15. **Cost** : Please request