MS CLINICAL RESEARCH

## Executive Report Summary

Test Product: Zixa Strong Pain Relief Balm — Type – Topical Leave-on
Sponsor- Jenburkt Pharmaceuticals Ltd

The above-mentioned test product was reported to be "**Non-irritant and safe for all skin types (normal, oily, dry, combination)**" with reference to the skin sensitivity evaluation by 24 hours occlusive primary irritation patch test (PIPT) conducted on 24 subjects at our facility between 04 Jun 2024 to 13 Jun 2024.

Reference Report Number: **SAFE/MSPT/SR/2024-124**

Study brief:
Study Protocol ID: SAFE/MSPT/2024-09
Study method ref: Study method is based on the Bureau of Indian Standards (BIS) method 4011:2018 for the test product. The study was conducted over a period of approximately 9 days for each subject. 40µl of the test product (no dilution) was patched on the upper back (between scapula and lower back) of human subjects, under occlusive patch for duration of 24 hrs. The skin was evaluated for signs of irritations identified under Erythema and oedema, using Draize's Scale. 1% SLS were used as positive control and 0.9 % isotonic saline as negative control in the study.

The mean score of irritation of the test product in the population at a time point was used to categorize the result outcome based on the given classification in BIS 4011:2018.

| **Test Product & Negative control** | | **Positive control** | |
|---|---|---|---|
| **Mean Score** | **Classification** | **Mean Score** | **Classification** |
| 2.0 / 8.0 | Non-irritant | 2.0 / 8.0 | Non-irritant |
| Up to 4.0 / 8.0 | Mild irritant | Above 2.0 / 8.0 | Irritant |
| Above 4.0 / 8.0 | Irritant | | |

The product emerged to be **Non-irritant** with the mean irritation score as tabulated below:

| | Score 0 | Irritancy | Score 24 hrs* | Irritancy | Score Day 7 | Irritancy |
|---|---|---|---|---|---|---|
| **Zixa Strong Pain Relief Balm** | 0.46 | Non-irritant | 0.21 | Non-irritant | 0.00 | Non-irritant |
| **Negative Control (0.9% saline)** | 0.00 | Non-irritant | 0.00 | Non-irritant | 0.00 | Non-irritant |
| **Positive Control (1% SLS)** | 2.54 | Irritant | 2.21 | Irritant | 0.50 | Non-irritant |

Note*: After patch removal

TESTED & APPROVED MSCR

Disclaimer: The research was conducted under controlled conditions following the standard operating procedure, available guidelines and approved protocols, to the best of our ability and knowledge. The reported values are accurate to the best of our understanding for the provided test sample and study population at the time and place of testing. A complete reproducibility of the results for a different sample from the same or different population may not be guaranteed. Individual response may vary.