CIPAC MT STATUS REPORT

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MT 0204 Freezing and thawing stability test

Allocated to CHIPAC

CIPAC methods published in:

CIPAC 70th meeting, June 2026 Krabi

Freezing and thawing stability test by Ms Haixia Wang (5449)

Ms Haixia Wang (replacing Ms Li Na) presented a proposal for a temperature cycling procedure for capsule suspension and related formulations. The proposed method uses four cycles consisting of 18 hours at minus 10 °C and 6 hours at 25 °C. Validation experiments examined the influence of temperature, cycle duration and the number of cycles. While pH, suspensibility, spontaneous dispersion and wet sieve results were largely unaffected, increases in free active ingredient levels were observed under more severe conditions. The presenter recommended adoption of the method by CIPAC.

The following comments were received from the meeting:

- A question was asked whether a 'bad' formulation had been tried. Ms Wang mentioned that maybe further experiments can be done using 'bad' formulations.
- Lower level of temperature of some formulations are protected down to -10°C, maybe it is possible to go lower. A comment will be included that lower temperatures can also be used.

Closed Meeting:

MT 204 Freezing and thawing stability test

Although a method description of the freezing and thawing stability test (CIPAC/5449) was not presented prior to the meeting, it was accepted as **provisional** CIPAC method pending full method write up, as an MT method.