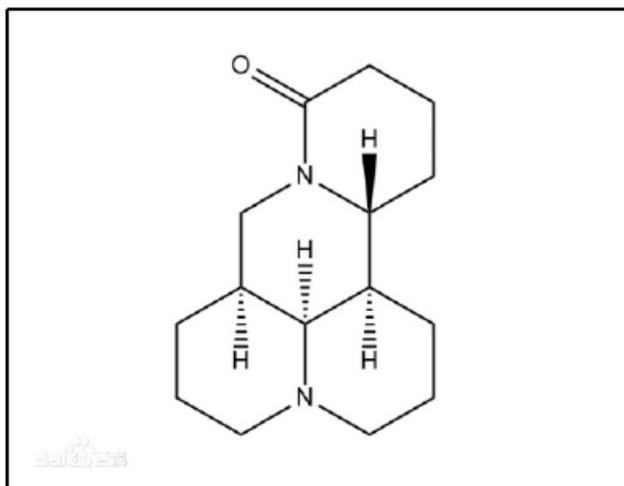


CIPAC STATUS REPORT

29.08.2023



1024 matrine

Allocated to CHPAC

CIPAC methods published in :

CIPAC

CIPAC 65th meeting, June 2021 virtual

Matrine by Mr. Jason Zhang (5273, 5274). Mr Jason Zhang presented the results of a small scale collaborative trial for matrine with four participants from China. The method was based on HPLC (C18) with UV detection (215 nm) and external standardization. The deviations of the original method as applied by the four participants were assessed as minor.

Two technical materials and three soluble concentrates were investigated. All samples fulfilled the statistical criteria (RSDR < RSDR(Horwitz) and HorRat ≤ 1.0).

Mr Zhang proposed to proceed to a full scale trial.

There weren't comments received from the meeting:

Closed Meeting:

A small scale trial was presented and the method was proposed for a large scale collaborative trial.

CIPAC 66th meeting, June 2022 virtual

Matrine by Ms Yue Wang (5313, 5314)

Ms Wang presented the results of a full scale collaborative trial for the determination of matrine in two TKs and three SL formulations. The method used consisted of reversed phase HPLC with UV detection at 215 nm, and external standardization. 18 laboratories participated and 17 laboratories reported their results in time. Deviations were reported by all laboratories, however, the deviations were considered minor. When including all data, the HorRat values were between 0.52-0.93 for four out of five samples with the exception of TK-2 for which a HorRat value of 3.05 was calculated. After elimination of Mandel's h and k statistic stragglers/outliers the HorRat values for all investigated samples ranged from 0.42-0.98.

Ms Wang recommended this method to be accepted as a provisional CIPAC method.

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The following comments were received from the meeting:

- Mr Garvey asked whether the removal of three outliers could be linked to certain method deviations. This was not the case.
- Ms Vinke asked whether the results of laboratory 17 could have been influenced by the use of a different HPLC column temperature (35°C instead of 30°C). This was assessed as not significant. Furthermore, Ms Vinke suggested that differences in storage temperature might have been of influence.

Closed meeting:

No further comments were received, the method can be promoted to a **provisional CIPAC method**.

CIPAC 67th meeting, June 2023 Braunschweig

Decision:

At the previous meeting, the method was accepted as provisional. No further comments were received. The method can be promoted to a **full** CIPAC method.