

CIPAC MT STATUS REPORT

02/03/2015

MT 197 Disintegration of tablets

Allocated to DAPF

CIPAC methods published in:

Not published

CIPAC 57th meeting, June 2013 in Kyiv

Mr Patrian on behalf of DAPF presented the proposal and validation for a new MT method for disintegration of tablets. The method is designed to determine the completeness of disintegration of tablets which are dissolved or dispersed in water independent of the use rate. The method is designed for, but not limited to, the disintegration of effervescent tablets.

One entire tablet is added to a defined volume of CIPAC standard water D and mixed by gentle stirring for the specified disintegration time of the tablet. The suspension is then passed through a 2000 µm sieve. The absence of a residue on the screen indicates complete disintegration of the tablet. 12 laboratories participated and 3 x ST samples from different suppliers were tested.

For the 1st sample tested no outliers were identified. For the 2nd sample, one outlier was identified, however the lab concerned noted that the appearance of the tablets was unusual and that during the test the tablet floated with no evolution of gas. It was concluded that the package of the tablet or the tablet itself had been damaged during shipping.

For the 3rd sample, 3 labs reported residue on the sieve. These 3 labs received the samples at least 2 months later than all other participants. Therefore it was concluded that the repackaging and the long transport (high temperature, humidity) had a significant influence of the results and are responsible for the residues observed.

Mr Patrian concluded that:

- Water temperature, speed of the stirrer and stirrer positions had no significant effect on the results
- storage problems during the transport of the tablets were detected by the new method: demonstrating its purpose and usability
- The collaborative test demonstrates the applicability and robustness of the proposed method to determine the completeness of the disintegration of tablets.

DAPF propose the method is adopted as a provisional method.

No comments were received from the meeting.

Decision: The method for the determination of the disintegration of tablets which have to be dissolved or dispersed in water (ST, WT, ...) (CIPAC/4894) was accepted as a **provisional** CIPAC MT method.

CIPAC 58th meeting, June 2014 in Liège

No further comments were received.

Decision: The method for the determination of the disintegration of tablets which have to be dissolved or dispersed in water (ST, WT, ...) (CIPAC/4894) was accepted as **full** CIPAC MT method.