

CIPAC MT STATUS REPORT

29.08.2023

MT 178 Attrition Resistance of Granules

Allocated to DAPF

CIPAC methods published in:

CIPAC H, p. 304

CIPAC K, p. 140

CIPAC 39th meeting, May 1995 in Limassol

Mr Rodler presented the results of a collaborative trial with 6 samples and 19 participants. The deviations from the prescribed method which were introduced by some participants seemed not to have influenced the results. Some amendments of the method were proposed concerning the bottle size and the rotational speed.

Decision The method for the determination of the attrition resistance of granules, CIPAC/3847, has been adopted as provisional CIPAC method.

CIPAC 40th meeting, May 1996 in Beijing

Decision The method for the determination of the attrition resistance of granules, CIPAC/3847, has been adopted as full CIPAC method.

CIPAC 46th meeting, June 2002 in Rome

Dr Menschel reported the results of a pilot study of an addition to the existing method MT 178 to encompass WG formulations. It was reported MT 178 was too aggressive for WG formulations. The method considered 8 samples from 4 manufacturing processes (pan granulated, extruded, fluid bed granulated and spray dried). The most notable deviation from the method was the use of different sieving machines, however this did not appear to affect the results. The correlation of the results with field performance was considered. It was agreed that the particle size of any dust formed was of concern for risk assessment and that the fraction <50µm was of toxicological concern. It was commented that the method was a visual assessment of the quality of the granule and cannot be directly correlated with the dust content. It was confirmed that the method was not designed to determine the dust content of the formulation but to check the attrition resistance of the formulation. Concern was expressed that the method may not be capable of distinguishing good formulations from poor products but it was noted that it was difficult to find poor WG products.

Decision The extension of the CIPAC Method 178, CIPAC/4280, has been accepted as **provisional** CIPAC Method (MT 178.2).

CIPAC 47th meeting, June 2003 in Bucharest

Decision The extension of the CIPAC Method 178, CIPAC/4280, has been accepted as **full** CIPAC Method (MT 178.2).

CIPAC 66th meeting, June 2022 Virtual

Attrition resistance of tablets by Mr Oliver Gutsche (5321, 5322)

Mr Gutsche presented the results of a small scale collaborative study with five participants for the determination of attrition resistance in EG, SG, WG, DT, ST, WT and GR (<1 cm) formulations with the aim to replace CIPAC MT 178.1 and 178.2 by a new, combined method MT 178.3. Adding glass beads to DT, ST, WT and GR (<1 cm) formulations improved the method as friction and resulting surface attrition were higher.

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Mr Gutsche recommended that this method will supersede CIPAC MT 178.1 and 178.2.

The following comments were received from the meeting:

- Mr Wenzel asked whether pharmaceutical methods were investigated. This was done in the preparation of the new method; however those methods are not suitable for these types of products.

Closed meeting:

This was a DAPF trial and the method wasn't changed. Mr Loreto wondered whether there was any difference between attrition using glass beads or not. Ms Vinke will clarify. Ms Tessier suggested to alter the use of tablet length into tablet diameter.

The method can be promoted to a **provisional CIPAC method** after the clarifications. The method will replace the existing ones.

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 with the editorial changes and with the remark that MT 178.3 supersedes MT 178 and MT 178.2.