CIPAC MT STATUS REPORT

16.01.2007

MT 193 Friability of Tablets

Allocated to DAPF

CIPAC methods published in:

CIPAC L, p. 146

CIPAC 48th meeting, June 2004 in Brno

Mr. Grohs presented a proposal for determination of friability of non coated tablets. The tablets are circulated in a rotating dish with a built-in, bow-shaped baffle. The resulting abrasion is a measure of the surface hardness. The method is an established method in the pharmaceutical industry. DAPF proposed the method to be accepted as provisional CIPAC method. Mr. Zaim thanked DAPF for the effort done and asked to include deltamethrin tablets in the study. Mr. Grohs responded that deltamethrin was already included. Mr. Hill asked if larger tablets break easier than small tablets, due to higher impact from the baffle. Mr. Viets responded that larger tablets are produced with higher pressure than smaller tablets and therefore not simple as that. Mr Grohs informed that large and small tablets would be investigated. Mr. Hill noted that this test is describing attrition and not friability. Mr. Zaim asked if the friability clause can be excluded if the tablet is blister packed. Mr. Grohs said that he will check it with the pharmaceutical companies.
Decision The method proposed is accepted as **provisional** CIPAC method as it is an established method in the pharmaceutical industry.

CIPAC 49th meeting, June 2005 in Utrecht

Mr R. Grohs gave a presentation on tablet characterisation based on the available information from the pharmaceutical industry. The presentation included a consideration of the disintegration of tablets and the method for determining the disintegration time. The problem for assessing tablet strength was also addressed. It was underlined that friability and hardness are properties that may serve as a measure of tablet strength and separate tests are developed for their measurement. The meeting was reminded that, since last year, a provisional CIPAC method is available for assessing friability. Mr Grohs proposed a test for assessing hardness and presented the results of a related small scale trial. Four laboratories participated which were asked to make 4 repeated analyses of each sample. CIPAC MT 171 test was used to assess the remaining dust.
The results obtained from the proposed friability test were contrasted with those of the CIPAC Attrition Test (CIPAC MT 178).
It was proposed to rename the "Degree of Attrition " to Friability and keep CIPAC MT 193 as a provisional method of determination of friability.
It was clarified that CIPAC MT 193 mainly determines the fine pieces into which the tablet disintegrates but not the larger ones, and Mr Grohs was asked if the test could be improved towards this end. Mr Grohs explained that work is already underway, but he also expressed his concern over the high cost of the tablets for this experience.
Decision The method for determination of friability of non coated tablets remains as **provisional** CIPAC method as the proposer announced that some amendments are foreseen to the method.

CIPAC 50th meeting, June 2006 in Geneva.

The method for determination of attrition resistance of non coated tablets, published in CIPAC L, p.147, remains as **provisional** CIPAC method.