CIPAC MT STATUS REPORT

18/09/2017

MT 200 Retention properties of pyriproxyfen MR formulations

Allocated to JAPAC

CIPAC methods published in:

Not published

CIPAC 59th meeting, June 2015 in Athens

Mrs Mukumoto presented (4999, 5000) a **small scale** collaborative trial of retention properties in pyriproxyfen MR. The long lasting effectiveness of release/retention properties of MR products is important for the quality of MR products and should be controlled. The procedure should be specific, simple and informative, and be able to distinguish a good from a bad product. The proposed method can be divided into two procedures: one in which half of the extracting solvent was replaced and replenished by fresh solvent and one in which the solvent was not replaced. The latter procedure is more comparable to the daily situation in which an MR product will be used and was therefore selected. Also, shaking during sampling was abandoned as this is not common during application of the MR product.
Three different MRs were investigated: MR-G, MR-R and MR-W. The pyriproxyfen content of all three products proved to be identical and uniformly dispatched. The products were investigated by removing one quarter of the product at 0 hr and after 1, 2, and 4 hrs after the start of the experiment and analysing them for pyriproxyfen content. The analytical procedure was based on ethyl acetate extraction, reversed phase C18 HPLC, UV-detection at 254 nm and internal standard based quantification. Four laboratories took part in the small scale collaborative trial. After data processing repeatability, ranging from 0.48% to 1.22%, and reproducibility, ranging from 0.87% to 1.49%, were calculated (two Cochran's outliers). The proposed method is considered appropriate for the determination of release/retention properties of pyriproxyfen MR.
JAPAC proposed the method to be accepted as a provisional CIPAC method.

The following comments were received from the meeting:

- Three laboratories changed the flow rate, why? Mrs Mukumoto replied that this was performed for adjusting the retention time of pyriproxyfen as requested by the method description, as a consequence, the method has been followed.
- Three different time points were analysed: 1, 2, and 4 hrs. Is this appropriate? Have you tried 8 or 16 hours? Mrs Mukumoto replied that less points were not adequate and more time points would make the procedure unnecessary long and complex.
- The product is going to be used in plain water. Why was 50% ethanol/water used as solvent? Mrs Mukumoto explained that the study was continued up to 6 months, when the a.s content was still 1.6%. With the accelerated system with water 1.6% was reached after 8 weeks, with ethanol/water 1.6% was reached in 4 hours. This was the reason for selecting 50% ethanol/ water as the solvent system.

Closed meeting:
The meeting discussed the comments received during the open meeting.
The meeting discussed about the possibility of using this method also for MR formulations. This was not known and Mr Hänel and Mr Bura will contact Mrs Mukumoto for further information.

Taking the special situation of the MR formulation into account, it is possible to adopt the method with the current validation data as tentative method with the need for further work on validation the method. It is not necessary to conduct a full trial, but rather to provide more validation data from additional laboratories to prove that the method works. These additional data could be presented at a CIPAC meeting and CIPAC could then promote the method as full (or first as provisional and the year later as full). The proposal was that at least four sets of acceptable validation data are needed to fulfill the requirement of at least eight labs for a full trial.

Decision: The method for the determination of retention properties of pyriproxyfen matrix release formulations (CIPAC/4999) was accepted as a **tentative CIPAC MT method** with the request of additional validation data.

CIPAC MT STATUS REPORT

18/09/2017

CIPAC 60th meeting, June 2016 in Tokyo

The method for the determination of retention properties of pyriproxyfen matrix release formulations (CIPAC/4999) was accepted as a tentative CIPAC MT method at the 59th meeting, 2015 in Athens with the request of additional validation data. The status of the method remains tentative as an additional 4 laboratories data will be presented in the next CIPAC TC meeting. It was proposed to use an extraction at room temperature for 24 hours or the same with a footnote of the other option.
This should be clarified with Sumitomo before goes to full method.

Remark: The extension of the scope (CIPAC/4997) of CIPAC method 715/TC/M/3 for the determination of the pyriproxyfen content of a matrix release formulation (MR) (incorporated type) was accepted as full CIPAC method

CIPAC 61th meeting, June 2017 in Rome

The method for the determination of retention properties of pyriproxyfen matrix release formulations (CIPAC/4999) was accepted as a tentative CIPAC MT method at the 59th meeting in Athens (2015) with the request of additional validation data. The status of the method remained tentative as it was mentioned that data from additional 4 laboratories will be presented in the next CIPAC TC meeting. It was proposed to use an extraction at room temperature for 24 hours or the same with a footnote of the other option. The data from the additional 4 laboratories were presented in Tokyo.

The following comments were received from the meeting:

➢ Mr Bura remarked that the method should have been promoted to full during the Tokyo meeting of 2016. No other questions were received.

Closed meeting:
The method for the determination of retention properties of pyriproxyfen matrix release formulations (CIPAC/4999) was accepted as a **full** CIPAC MT method