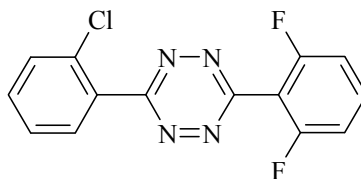


CIPAC STATUS REPORT

01/07/2005



0734 Diflovidazin (Flufenazine, SZI 121)

Allocated to HU

CIPAC methods published in:

CIPAC L, p. 61

CIPAC 47th meeting, June 2003 in Bucharest

Mrs Á. Hegedüs presented a Collaborative study for the determination of flufenazine in two technical materials, and two SC formulation samples by reverse phase HPLC using a C18 column and UV detection. Ten laboratories participated in the study, but only nine results arrived in time and were included in the calculation. The results of the tenth laboratory were well fitting in the range of results of the other laboratories. Mr Hill asked what were the criteria for rejecting the outliers and asked for them to be included, since there was no reason to exclude them, and in order to give a more representative picture of the performance of the method. Mrs Á. Hegedüs agreed to this.

Decision The HPLC method CIPAC/4324 was accepted as **provisional** CIPAC method with the following note:

There should be a note in the method stating that alternative columns may be used, but for a clear resolution of the impurity the Zorbax column should be used

CIPAC 48th meeting, June 2004 in Brno

The reversed phase HPLC method (CIPAC/4324) for the determination of diflovidazin was accepted as **full** CIPAC method. ISO/TC81 decided that the name diflovidazin should be added to the list of proposed common names