

New regulations to come!



Erwin Malzacher,
Head of Sales & Marketing

Dear Reader,

The increasing demand for validated HPTLC methods for identification of botanicals is not surprising to CAMAG. This industry has been relatively free of regulation in the US, but now the FDA expects manufacturers to comply to current Good Manufacturing Practice (cGMP). Our specialists are familiar with this issue as they have been in close contact with the related regulatory bodies and the industry for several years.

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► **We have validated methods! Ask for them!**

HPTLC method validation requires reproducible results, which in turn require state-of-the-art instrumentation and standardized procedures. Two recent developments assure reproducibility of your result: First, the Automatic Developing Chamber ADC2 is universally applicable and gives results of unsurpassed reproducibility. Second, the DigiStore2 Documentation System has been designed to eliminate as much potential for variations in image capture as possible. These instruments assure that your HPTLC system produces reliable results, day after day.

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News & Events

International Symposium for High-Performance Thin-Layer Chromatography, Berlin (Germany) 9–11 October 2006

CBS 95, in this issue of the CAMAG Bibliography Service:

- Determination of histamine and other biogenic amines in fish
- Ultra trace analysis of glyphosate and AMPA in water
- In situ derivatization of glyphosate and AMPA
- Quality and reproducibility of chamber saturation with new ADC2
- Quantitation of in vitro lipolysis products with AMD

Courses

Fundamentals of Modern TLC

(German) 21–22 Nov 2005, Muttentz

Method Development in TLC/HPTLC

(German) 23–24 Nov 2005, Muttentz

CAMAG

October 2005

Validated HPTLC Methods for Identification of Botanicals soon to become “Official Methods”?

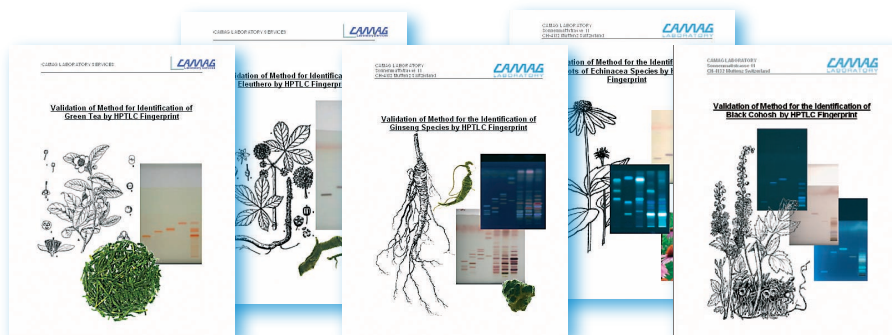
For more than 5 years the CAMAG Laboratory has been working on the development of HPTLC fingerprints for the identification of botanicals. We are collaborating with the American Herbal Pharmacopoeia, the European Pharmacopoeia, and the USP, which all have incorporated our experimental data into their botanical monographs.

In view of the new cGMP regulations for the American botanical industry, which emphasize the essential need for proper identification of materials, we started a project concerning the validation of methods for generating HPTLC fingerprints. As prerequisite a suitable concept and a protocol addressing the critical elements of such methods that are of qualitative nature, had to be developed. We accomplished the task together with NSF International and presented the results at the 2nd Conference on Natural Health Products Research (Vancouver 2005). The principal validation points are stability, specificity,

reproducibility, and robustness. Based on the positive feedback we were able to secure a grant from the Office of Dietary Supplements (US National Institutes of Health) for actually performing method validation. Recently a first set was completed. It includes methods for the identification of Eleuthero, Green Tea, Echinacea, Ginseng and Black Cohosh. We are currently working on methods for Ginger, Feverfew, Milk Thistle, Saw Palmetto and Kava. The validation packages have been delivered to AOAC International, who is currently discussing the possibilities of making the corresponding methods “AOAC Official Methods of Analysis”.

For further information about the validation protocol and copies of validated methods please contact us at <mailto:lab@camag.com>

Numerous application notes for identification of botanicals can be downloaded from www.camag.com/herbals.



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