W05 HPTLC in stability testing of herbal medicinal products

K. Thiekötter [a], *E. Reich* [b] *and M. Veit* [a]
[a] Forschungsvereinigung der Arzneimittel-Hersteller e. V., Kranzweiherweg 10, D-53489 Sinzig, Germany. [b] CAMAG, Sonnenmattstr. 11, CH-4132 Muttenz, Switzerland.

In herbal medicinal products (HMP's), the entire herbal drug or a herbal drug preparation is regarded as the active substance (API), regardless of whether or not constituents with defined therapeutic activity are known. In stability testing of these products, it has to be shown by means of appropriate fingerprint chromatograms, that substances present in extracts and finished products are stable and that their proportional content remains constant over a defined period of time. For analysing fingerprints of herbal drugs or herbal drug preparations, validated methods e.g. concerning robustness, reproducibility and selectivity methodology are a major prerequisite. In this context, HPTLC offers the advantage of different visualised fingerprint. By using different detection reagents and detection wavelength selectivity in HPTLC is superior to other chromatographic techniques.

According to the EU guidelines "Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products" (CPMP/QWP/2820/00) and "Note for Guidance on Quality of Herbal Medicinal Products" (CPMP/QWP/2819/00) all test methods (assays) must be validated with appropriate methods according to the EU-guidelines "Note for Guidance on Validation of Analytical Methods: Definitions and Terminology" (CPMP/ICH/381/95; ICH Topic Q2A) and "Note for Guidance on Validation of Analytical Procedures Methodology" (CPMP/ICH/281/95; ICH Topic Q2B). In order to fulfil the requirements and instructions given in the latter guidelines, special analytical features of plant derived multi-component mixtures have to be considered. According to the advantages of HPTLC given above, this methodology is suited for analysing these mixtures.

Using starting materials and preparations form *Urtica* as an example, appropriate approaches for demonstrating selectivity, robustness and reproducibility of HPTLC methods for quality and stability testing are presented.

W06 Stability of flavonoids by TLC analysis in Hawthorn leaf and flower, Passion flower herb, Hypericum herb and Chamomile flower fluid extracts

A. Mulà and A. Nagell
EUROMED S.A., C/ del Rec de Dalt, 21-23, E-08100 Mollet del Vallès (Barcelona), Spain.

Thin layer chromatography (TLC or HPTLC-quantitative TLC) is a widely used chromatographic method from which is possible to obtain basic information about the identity, purity and stability of active or marker substances in drugs and their preparations. Adulterations and decompositions can be easily detected using this technique because you can see in one line (from the start to the end of the plate) all possible substances by different possibilities (UV 254 nm, UV 366 nm and the possibility for colouring the substances and detecting them again by UV 366 nm or daylight). By this way you can provide semi-quantitative (TLC) or quantitative (HPTLC) information on the major constituents or marker substances of drugs, extracts or finished preparations.

In this work TLC is proposed as a technique to follow the stability of several common extracts containing flavonoids. Hawthorn leaf and flower, Passion flower herb, Hypericum herb and Chamomile flower were used to prepare fluid extracts which were examined by TLC, using typical mobil phases and detection systems for flavonoids.

The fluid extracts were submitted to a stability program at 25ºC and 40ºC following the behaviour of the C-O-glycosides and aglycone forms of flavonoids present in the studied extracts by the proposed chromatographic method.

If there is a decomposition may be from rutosid to quercetin it has to be discussed if this is important of a pharmaceutical and medical view.