

EIKE REICH, ANNE BLATTER, CAMAG Laboratory, Muttenz, Switzerland: Proposal for the Development, Evaluation and Validation of qualitative HPTLC Methods for the Identification of Botanical. Although pharmacopoeias and the botanical industry recognize TLC as a powerful tool for the identification of botanicals, very few of the TLC methods in use have actually been validated. One of the reasons is, that there are no "official" guidelines according to which such validation should be performed.

We propose a three-step process to help making available to the botanical industry reliable, state of the art HPTLC methods, which are fit for the purpose of ensuring identity and other quality criteria of botanicals based on fingerprint chromatograms. 1) All HPTLC analyses should be based on a standardized methodology providing guidance for the selection of important parameters, thus ensuring the highest possible reproducibility and comparability of results. 2) Methods for identification should be evaluated not only based on their ability to show the similarity or difference of test solution and reference solution side by side on the same plate, but also based on the reproducibility of the result documented as image. It is important, that such methods can accommodate the natural variability of a given plant species and at the same time discriminate any adulterant. 3) During validation specificity of the method must be proven. In addition various stability issues have to be addressed together with any reproducibility and robustness problem that might occur.

The proposal is illustrated using several examples and is intended as a starting point for a discussion that helps making qualitative HPTLC method for identification more widely applicable.

Reference: Koll, K., Reich, E., Blatter, A., Veit, M., Validation of standardized HPTLC-methods for quality control and stability testing of herbals (herbal drugs, herbal drug preparations, herbal medicinal products and other herbal products), J. of AOAC International, accepted for publication, April 2003