

Transfer of TLC Screening Methods Designed for Use in Developing Countries to Quantitative HPTLC-Densitometry Methods for Diazepam and Amodiaquine Tablets

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Summary. Transfer of two rapid thin-layer chromatography (TLC) screening methods used to detect markedly substandard and fake pharmaceutical products to quantitative high-performance TLC (HPTLC)-densitometry methods is demonstrated using a model procedure that was published earlier. These TLC methods for diazepam and amodiaquine are contained in a Compendium of methods by Kenyon and Layloff and a Minilab method manual from Global Pharma Health Fund E.V., respectively, for use in countries with limited resources. Merck HPTLC Premium Purity silica gel 60 F₂₅₄ glass plates, automated standard and sample solution application with a CAMAG Linomat 4, and automated densitometry with a CAMAG Scanner 3 were used for detection, identification, and quantification. Sample peak identity and purity validation were carried out by spectral comparison checks available in the winCATS software. Accuracy was estimated by the standard addition approach with overspotting standard and sample solutions. HPTLC gives better efficiency, selectivity, and resolution than TLC, and the new methods overcome the deficiencies in technology related to manual application and visual zone comparison that do not allow the Compendium and Minilab TLC procedures to support regulatory compliance actions. These new methods can be fully validated according to the International Conference on Harmonization guidelines or by interlaboratory studies if required by their applications.

Key Words: diazepam, amodiaquine, thin-layer chromatography, densitometry, pharmaceutical product screening, drug analysis, fake drugs, transfer of TLC methods to HPTLC-densitometry

Introduction

A previously published paper [1] described a model method for transfer of qualitative thin layer chromatography (TLC) pharmaceutical product screening methods to quantitative high performance TLC (HPTLC)-densitometry methods that can be used to support regulatory compliance actions. These screening methods have been published in a U.S. Food and Drug Administration Compendium [2] and in manuals published by the Global Pharma Health Fund E.V. (GPHF) [3] primarily for use in developing countries to help detect mislabeled, markedly substandard, and fake products; these methods are limited to the use of the inexpensive, relatively

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