

Pharmaceuticals and Drugs

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I. INTRODUCTION

Chromatography is used extensively in the pharmaceutical industry as a separation tool for qualitative and quantitative analysis of various pharmaceuticals and drugs. Although the popularity of capillary action planar chromatographic methods has decreased considerably during the past 10–15 years because of the replacement of several standard thin-layer chromatographic (TLC) separations with high-performance liquid chromatographic (HPLC) methods, they do claim a share of the market for chromatographic techniques, because many difficult analytical problems can be solved in small laboratories equipped with basic TLC equipment. Traditional TLC is inexpensive, and simple to use and requires minimal instrumentation, laboratory space, and maintenance. However, to achieve good precision, accuracy, and reproducibility, a certain degree of instrumentation is required; the use of densitometric evaluation is necessary at least for quantification.

A literature search of the last 20 years indicates that extensive reviews on TLC systems for pharmaceuticals and drugs have been published (1–11). Several monographs, review papers, and book chapters are concerned with the detection and quantification of separated compounds (5,6,12–19).

Pharmacopoeias do not show the real importance of TLC in pharmaceutical analysis. Although the fourth edition of the European Pharmacopoeia (Ph. Eur. 4) (20) describes quantitative TLC in detail, its monographs include only qualitative identification or semiquantitative purity tests. The 25th edition of the United States Pharmacopoeia (USP 25) (21) contains a description of TLC in a general chapter, <621>, which has remained unchanged for about 20 years. However, recently Sherma gave a comprehensive outline of modern thin-layer chromatography in pharmaceutical and drug analysis in the Pharmacopoeial Forum (11). This article should be the basis for a future revision of the TLC chapter in Chromatography <621> for USP 26.

Governmental authorities require testing of pharmaceuticals for stability and impurity profiles before approval is given. Hence, the monitoring of the stability of drugs by TLC upon storage (22–26) and under stress (27,28) is of concern. In addition, determination of bulk active ingredient purity and of the impurity profile using TLC has been reported (4,5,29–35).

To illustrate the applicability of planar chromatographic methods in pharmaceutical analysis, a brief outline is given below. Some aspects are well known and are treated only briefly, whereas others require a more detailed discussion. These aspects are listed in Table 1.