Rapid and Effective Therapeutic Drug Monitoring System Utilizing Sealed Thin Layer Chromatography Cartridges

A novel sealed TLC cartridge system for rapid therapeutic drug monitoring, enhancing precision medicine and point of care testing

Category
Point-of-Care (POC) Diagnostics

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Background

A major clinical challenge in chemotherapy dosing is the lack of information on drug elimination and metabolism in patients at the time of administration. Initial doses are based on body surface area, which has been shown to have no correlation with plasma drug concentration, leading to significant variability in drug levels and clearance rates among patients. These differences impact patient outcomes and side effects. Therapeutic drug monitoring (TDM) aims to provide plasma drug concentration data to adjust dosing for better clinical outcomes. TDM is commonly used with drugs like antiepileptics, antiarrhythmics, immunosuppressants, and antibiotics, where drug concentration correlates with clinical effects. However, TDM is time-consuming, expensive, and labour-intensive, limiting its clinical use. The gold standard for drug quantification involves high pressure liquid chromatography (HPLC), which requires specialized training and maintenance, making it impractical for widespread clinical application.

Technology Overview

The invention aims to overcome the disadvantages of HPLC and other labour-intensive methods by providing a rapid, effective analytical system for clinical use, specifically giving physicians access to data on drug clearance and metabolism. This method utilizes thin layer chromatography (TLC) simplified into a single-use cartridge. TLC involves spotting a sample on a coated plate, which is then placed in a solvent. The solvent moves up the plate by capillary action, separating the mixture's components based on their solubility and adsorption. The components' positions are visualized, and their Rf values are used for identification. The innovation lies in a sealed cartridge system that prevents exposure to harmful materials and eliminates the need for cleaning or maintenance. This self-contained system can be used at the point of care, requires minimal training, and provides nearly real-time data, enhancing its practical application in clinical settings.

See Figure 1.

Benefits

The present invention is particularly adapted for convenient TLC analysis, for example (but not exclusively) for the purpose of therapeutic drug monitoring, whereby the key elements of the TLC system (including the mobile phase) are integrated into a single cartridge, and wherein vapour release from the mobile phase is avoided during the process. The mobile phase (or solvent system) is the phase that moves along the stationary phase (TLC layer) and separates the sample.

In particular, the loading of the analysis sample onto the TLC plate, development of the plate, and subsequent analysis or quantification of analytes and standards can occur in a sealed environment. This is achieved by the use of sealed reservoirs and appropriate septa made of self-sealing materials.

Applications

Therapeutic Drug Monitoring: Therapeutic drug monitoring (TDM) is particularly suited for precision medicine, correlating drug concentrations in blood with efficacy. TDM is crucial for drugs with high variability in metabolism, distribution, absorption, and excretion, common in chemotherapy agents. Plasma concentrations can vary significantly, but chemotherapy dosages are often based on patient surface area estimations. TDM is rarely used, with exceptions like methotrexate and busulfan, due to a lack of available assays and challenges in correlating blood concentrations with efficacy. This technology addresses these issues, enabling better trial designs and drug efficacy.

Point of Care Testing Market: The TLC cartridges' compact, self-contained design makes them ideal for point of care (POC) testing, which allows medical tests to be conducted near the patient, such as at the bedside or GP surgery, rather than in a lab. POC testing offers rapid results, facilitating timely diagnosis and dynamic patient monitoring, which is essential for personalized and targeted medicine.

Opportunity

UCLB is looking for opportunities to market this technology to:

- TLC equipment manufacturers which are interested in offering a new drug monitoring solution to clinical facilities and hospitals as a means to monitor patients’ metabolic degradation of drugs in an effort to customize dosing regimens for the most effective outcome
- Pharmaceutical companies as a means to improve the performance and efficacy of their new and old drugs.

Patents

EP3717897 (Granted) / Thin-layer chromatography system and method for assessing analyte concentrations in samples

US16/768136 (Pending) / Thin-layer chromatography system and method for assessing analyte concentrations in samples

Seeking

Licensing, Commercial partner

IP Status

Patented