

Analysis of antineoplastic drugs from wipe samples using MicroLC



Development of a quantification method using MicroLC-MS

Product Information



Micro LC
Antineoplastic Drugs
MicroLC-MS/MS

MicroLC analysis of cytostatics using YMC-Triart C18

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Author: Anna Bergmann

Hetzel et al. developed and validated a MicroLC-MS/MS method using YMC-Triart C18 to analyse antineoplastic drugs from wipe samples to determine surface contaminations with these drugs.

This will ensure the safety of healthcare workers and all people who might come into contact with hazardous drugs such as cytostatics.

This product information presents the results of this study and shows:

**YMC MicroLC columns are perfectly
applicable for routine analysis!**

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1 Introduction

The fight against cancer is one of the major issues of today as cancer is responsible for 13% of all deaths worldwide. In cancer therapy, the application of antineoplastic drugs is an established treatment strategy.

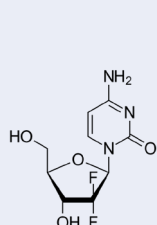
The application of these drugs is essential for the patients. However, it has to be noted that these antineoplastic drugs are hazardous, not only for the cancer patients, but also for all other people who come in contact with these substances. Because of this hazard potential, reliable and sensitive analytical methods are needed to monitor the exposure to antineoplastic drugs.

The common methods are LC-MS based, but except for the aim to reduce the hazardous potential, other aspects such as saving of resources and costs has to be considered.

Therefore, Hetzel et al. developed a quantification method for 11 cytostatics using MicroLC-MS.*

The results are published in the journal Analytical and Bioanalytical Chemistry in a research article "Micro-liquid chromatography mass spectrometry for the analysis of antineoplastic drugs from wipe samples".

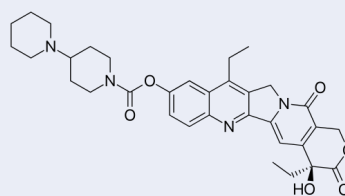
Below, the 11 antineoplastic drugs, which can be determined by the methods described in the following pages, are listed.



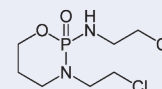
Gemcitabine



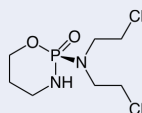
Topotecan



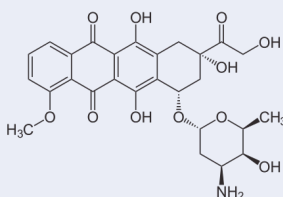
Irinotecan



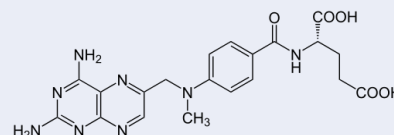
Ifosfamide



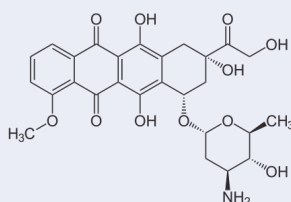
Cyclophosphamide



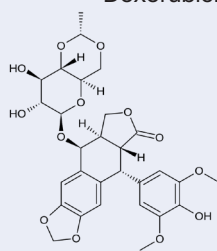
Doxorubicin



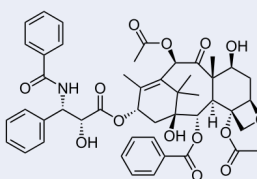
Methotrexate



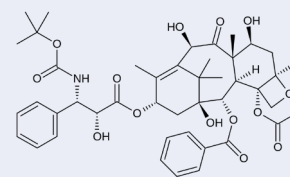
Epirubicin



Etoposide



Paclitaxel



Docetaxel

* All 11 cytostatics including the isobaric compounds ifosfamide, cyclophosphamide, doxorubicin and epirubicin are well separated.

2 Method development and validation using MicroLC-MS/MS

Based on a previous study in which the best selectivity for this analysis was determined, the MicroLC-MS/MS method was subsequently developed with YMC-Triart C18 (50 × 0.3 mm, 1.9 µm). As the German substance-independent reference value for wipe samples is 0.1 ng/cm² the method was optimised to a LOQ of 0.01 ng/mL.

In the following step, the method was validated using standard samples which contain the 11 antineoplastic drugs. The results are presented in the chromatogram below.

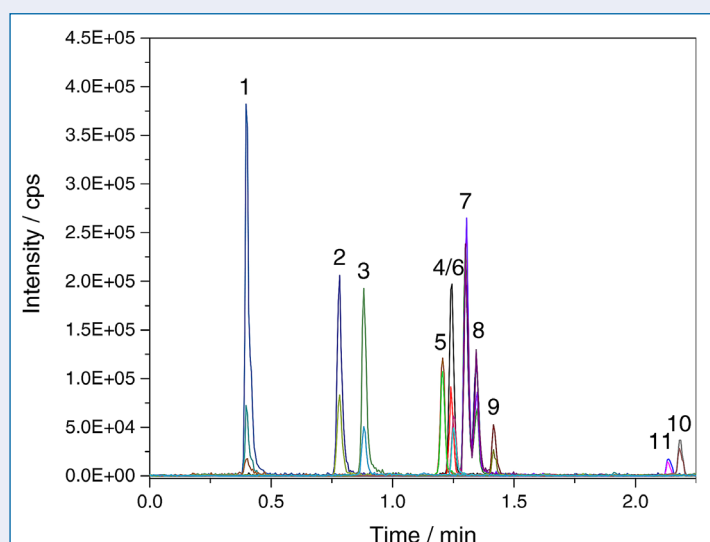


Figure 1: Separation of the standard samples containing the 11 antineoplastic drugs [1].

The results of the method validation and the QC data show

- all 11 substances are identified
- identification and separation of isobaric compounds
- recovery between 80 and 120%
- high intra- and inter-day stability
- minimum retention time variability
- high method stability
- LOD and LOQ around 10 pg/mL for every compound
- excellent applicability of MicroLC for routine analysis

3 Method transfer to real samples: antineoplastic drugs in wipe samples

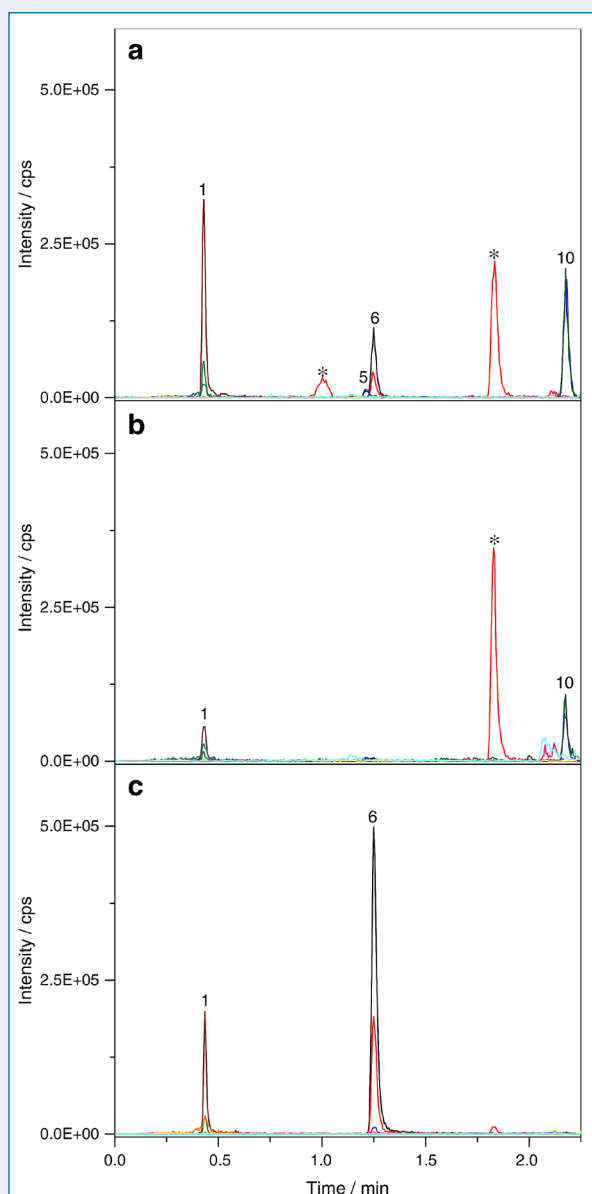


Figure 2: Chromatograms for 3 different real samples [1].

In order to determine surface contaminations with antineoplastic drugs and the success of cleaning procedures, wipe sampling is currently the method of choice. To show the applicability of the developed method, three different real samples are presented which were taken from different locations in a hospital and application areas at hospital wards.

Figure 2 shows the applicability of the developed method for real samples and the possibility to use this method in the daily life of the pharmaceutical sector.

4 Summary

This product information showed that MicroLC columns from YMC are perfectly applicable for routine analysis.

For MicroLC, YMC provides:

- all YMC phases for RP, NP, and HILIC available for MicroLC
- compatibility with Micro-/NanoLC/MS systems
- 1.9, 2, 3, or 5 µm particles
- length from 50 to 150 mm
- ID from 75 to 500 µm
- guard columns, usable for trapping/desalting

5 Literature

[1] T. Hetzel, et al., Micro-liquid chromatography mass spectrometry for the analysis of antineoplastic drugs from wipe samples, *Anal. Bioanal. Chem.* (2016)