ANALYSIS OF PHARMACEUTICAL SOLVENTS USING A NEW LOW-BLEED CAPILLARY COLUMN

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INTRODUCTION

Analysis of pharmaceutical solvents has become an important issue in the production of existing drugs and the development of new drugs. The use of solvents is a necessity for the synthesis of many of the biologically active compounds but their removal from the finished drug is also important as many of the solvents used have undesirable health implications. Low-level detection limits are therefore required for quality control and to ensure that the behavior of new drugs being trialled is not due to any residual solvent present.

Most of these solvents are low molecular weight, volatile compounds that can be difficult to remove from the final target drug. The volatile nature of these solvents requires analyses have to be performed on a specifically designed volatile column. These types of capillary columns are usually thick-filmed and have low thermal stability. The low thermal stability of these custom-designed volatile columns usually results in higher bleed levels in the later part of the chromatogram. As a consequence detection limits are higher than is desirable. A move to more thermally stable phases such as 5% phenyl phases does not provide the same separation of the various components that the volatile columns achieve.

BPX624 ADVANTAGE

The new BPX624 capillary column from SGE has been specifically designed to solve these problems. The BPX624 column is the highest temperature volatile capillary column currently on the market. The maximum temperature limit of 280°C provides added flexibility to the chromatographer not previously available with other volatile columns. The thick film and excellent inertness combine to give excellent separation and peak shape of difficult-to-analyse components. Lower signal-to-noise ratios allows for lower detection limits at temperatures where most volatile capillary columns are reaching their maximum temperatures.

The excellent partitioning properties of BPX624 can be seen in **Figure 1**. These common and difficult-to-separate pharmaceutical solvents are easily separated on BPX624.

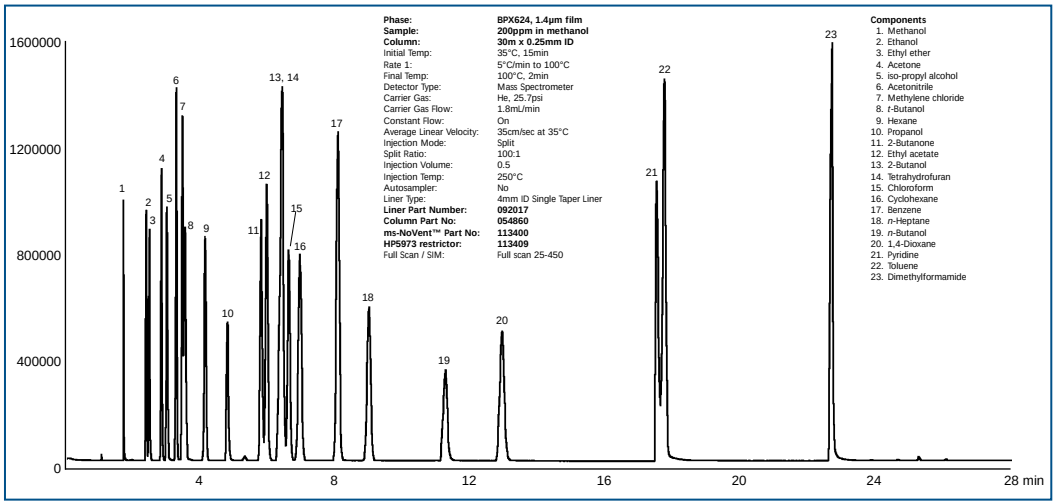

Figure 1. Common pharmaceutical solvent analysis on the thick film BPX624 capillary column. Difficult-to-analyse solvents are easily and quickly resolved using the BPX624.

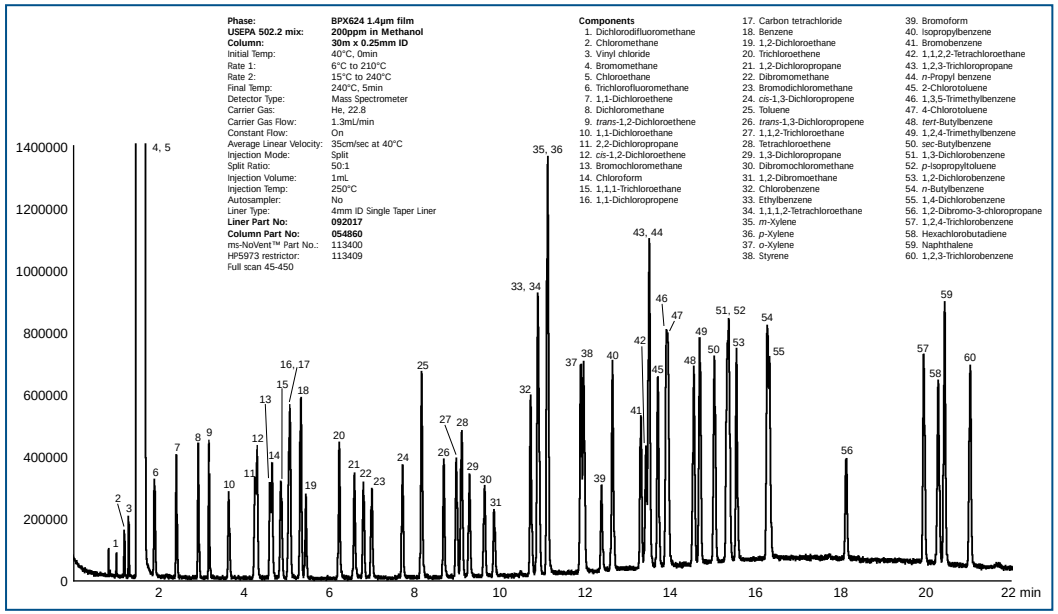

Figure 2. Note the excellent resolution of the front-end components. The gaseous compounds are easily separated on BPX624. Also note the low bleed characteristics of the high temperature BPX624 phase with improved signal-to-noise ratio.

DRINKING WATER ANALYSIS ON BPX624

The BPX624 capillary column is also the first choice for many drinking and groundwater analyses such as the US EPA 502.2 and 624 test mixes. The thick film and high maximum temperature make this the ideal column for the analysis of gases and low boiling point contaminants. **Figure 2** shows the exceptional separation of the early eluting volatile components while still maintaining extremely low bleed levels as the later higher boiling compounds elute. The peak shape is excellent indicating the high level of inertness of the BPX624 phase.

The increased thermal stability of this new phase gives the flexibility of a wider variety of analyses to be performed at higher temperatures unable to be achieved on a standard volatile column. In addition, the more thermally stable BPX624 phase will allow baking out of the column at higher temperatures, otherwise not possible with conventional phases. This allows for rapid low level analysis of volatile components in a volatile matrix not previously achievable on conventional volatile columns.

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