



OCTOBER 2008

**AUTOMATED
GEL PERMEATION
CHROMATOGRAPHY (GPC)**

**HEALTH TECHNOLOGY ASSESSMENT UNIT
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021/08**

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EXECUTIVE SUMMARY

Gel permeation chromatography (GPC) is claimed to be useful for the determination of trace levels of priority pollutants (PCB, PAH, and pesticides) in complex environmental samples and food samples which require analyte purification and concentration. This technique is currently being introduced to clinical samples to remove high molecular weight interferences such as lipids, polymer and pigments from the sample before analyzing it by Gas Chromatography (GC), Gas Chromatography/ Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC). This process is known as sample clean-up.

There was no retrievable evidence on the efficacy and effectiveness of Automated Gel Permeation Chromatography System (GPC) with regards to clinical sample preparation or sample clean up. The cost of a GPC system is about RM [REDACTED].

GPC needs to be validated and tested before considering its use for sample preparation or sample clean up for clinical samples.

Clinical research using clinical specimens should be conducted to evaluate the efficacy of GPC for clinical sample preparation or sample clean up.

AUTOMATED GEL PERMEATION CHROMATOGRAPHY

1. INTRODUCTION

Gel permeation chromatography (GPC) is claimed to be useful for the determination of trace levels of priority pollutants (PCB, PAH, and pesticides) in complex environmental samples and food samples which require analyte purification and concentration. GPC is also used for environmental sample analysis, generally used as a clean-up method to remove large molecules which interfere with target analytes from the extract prior to analysis on the instrument. This technique is also used for polymer molecular weight determination.

GPC is defined as sized based separation performed in an aqueous mobile phase and is typically applied for protein analysis or for water soluble polymers.¹ This technique is currently being introduced to clinical samples to remove high molecular weight interferences such as lipids, polymer and pigments from the sample before analyzing it by Gas Chromatography (GC), Gas Chromatography/ Mass Spectrometry (GC/MS) , or High Performance Liquid Chromatography (HPLC). This process is known as sample clean up.^{2,3}

2. OBJECTIVE

The objective of this review was to determine the safety, efficacy and effectiveness of Automated Gel Permeation Chromatography for sample clean up process.

3. TECHNICAL FEATURES

Automated Gel Permeation Chromatography System (GPC) is from Germany. GPC is a separation technique based on hydrodynamic volume (size in solution). Molecules are separated from one another based on differences in molecular size.



**Sample Preparation System
&
Automated Concentrator**



3.1 **Sample Preparation System - GPC – Evaporation – Liquid Handling**

The functional process of the system is geared to the modified modular extension of the modified DFG S19 multi method (§ 35 00.00-34 L). GPC ULTRA is included the complete process from the sample extract via the GPC column with online vacuum concentration to the aliquotation of the precisely concentrated volume (5 mL) into different vials.

GPC ULTRA Thereby Automates the Following Steps:

1. Injection of the sample (26 or 52 in series) via robot needle and sample loop onto the GPC column
2. Cleanup of the sample via gel permeation chromatography (GPC)
3. Transfer of the main run into a laser controlled vacuum chamber
4. Online concentration of the column eluate with vacuum, final volume control and precise fill-up to 5 mol
5. Aliquotation up to three vials
6. Rinsing of needle loop, ports, vacuum chamber and all tubing's

4. **Methodology**

4.1. **Searching**

Electronic databases were searched, which included Pubmed, Ovid, Medline, CINAHL, and Cochrane database of systematic reviews, HTA Databases, Horizon scanning databases (CADTH, ASERNIP-S, Defra, euroscan), FDA website and Google for relevant articles.

The search strategy used the terms, which are either used singly or in various combinations: Gel Permeation Chromatography, accuracy, precision, efficacy, sample clean up and sample preparation

4.2. **Selection**

All articles published and unpublished related to safety, efficacy and effectiveness of Gel Permeation Chromatography were selected. Critical appraisal of relevant literature was performed and evidence graded according to US/Canadian Preventive Services Task Force (Appendix 1)

5. RESULTS AND DISCUSSION

There was no articles retrieved from the databases. However, some reports were submitted by the vendor. These reports were more relevant to the agricultural and foodstuffs which were evaluated at MARDI. The evaluation or experiment using the clinical samples is still ongoing at the Hospital Sungai Buloh clinical laboratory.

5.1. SAFETY

There was no retrievable evidence on approval by US FDA for Automated Gel Permeation Chromatography (GPC).

5.2. EFFICACY AND EFFECTIVENESS

There was no retrievable evidence regarding the efficacy and effectiveness of sample preparation or sample clean up using Gel Permeation Chromatography. There were several reports by MARDI, which analysed on foodstuff for determination of pesticides, water content (extraction and subsequent liquid/ liquid partition for materials in water), extraction of fat and etc.⁴ However, there was no report submitted with regards to clinical sample preparation or sample clean up using Gel Permeation Chromatography done at any clinical laboratory.

5.3. COST

The cost of a GPC system is about RM [REDACTED].

6. CONCLUSION

There was no retrievable evidence on the efficacy and effectiveness of Automated Gel Permeation Chromatography. GPC needs to be validated and tested before considering its use for sample preparation or sample clean up for clinical samples.

7. RECOMMENDATION

Clinical research using clinical specimens should be conducted to evaluate the efficacy of GPC for clinical sample preparation or sample clean up.

8. REFERENCES

1. Columbia Analytical Services, Inc 2008 Available at <http://www.caslab.com/Laboratory-Instruments/>
2. L. H. Sperling. Gel Permeation Chromatography and High Performance Liquid Chromatography: Modern Technology and Usage. Center for Polymers Science and Engineering & Polymer Interfaces Center, materials Research Center, Department of Chemical Engineering and Materials Science And Engineering Department, Lehigh University, %E. Packer Ave , Bethlement, PA 18015-3194)
3. The Chemist's Source for Laboratory Products Available at <Http://www.laballiance.com>
4. Collection of official Methods under Article 35 of the German Federation Food Act. By MARDI

9. APPENDIX

9.1 Appendix 1

DESIGNATION OF LEVELS OF EVIDENCE

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-I Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)