Case Study

(w) www.eprep-analytical.com
(e) info@eprep.com.au

EPREP |Case Study

Automating PAH Extraction in Liquid Paraffin with ePrep ONE

Ego Pharmaceuticals Transforms PAH Testing with ePrep ONE Automation

Ego Pharmaceuticals replaced manual liquid–liquid extraction (LLE) for polycyclic aromatic hydrocarbons (PAHs) in liquid paraffin with a fully automated workflow on the ePrep ONE Sample Preparation Workstation. The result: improved precision, ~80% reduction in solvent use, and hands-on time cut from 2 hours to 10 minutes per batch — all while meeting stringent pharmacopeia standards

Application Implemented

PAH impurity analysis for liquid paraffin is a required test to meet pharmaceutical compliance (BP & USP) as well as a critical safety requirement due to the significant health risks posed, including carcinogenic and genotoxic effects. Manual extraction is time-consuming and requires high solvent consumption. The traditional method(s) also result in regular analyst exposure to hazardous solvents such as hexane and DMSO. With any manual process, there is an increased risk of human error and inconsistent precision between analysts.

Automated Liquid–Liquid Extraction (ALLEx) on ePrep ONE, combines robotic liquid handling and syringe mixing to deliver rapid, sealed extractions ready for UV–Vis measurement. The workflow was validated for precision, linearity and detection limits to ensure compliance to pharmacopoeia standards (USP, BP, EP).

Challenges Faced

- Manual LLE requires extensive hands-on time (≈2 hours per batch) and exposed analysts to hazardous solvents (hexane, DMSO).
- High solvent consumption (628 mL/run) and waste disposal costs.
- Inter-analyst variability and risk of manual errors.
- Need to meet USP/BP/EP monographs with secure, compliant data handling.

Key Wins at a Glance

Parameter	Manual Extraction	ePrep ONE
Solvent Usage	628 mL	**123 mL**
Hands-on Time	2 Hours	**10 Minutes**
RSD (Precision)	>2% (manual)	**0.9% (automated)**

Improvements & Gains from ePrep Automation

- Precision & Accuracy: Standard extraction RSD 0.9% (extreme RSD 1.9%), matching or surpassing manual methods.
- Solvent Savings: ≈80% reduction.
- Time Efficiency: Total run time remains ~2 hours but fully unattended besides initial 10 mins set-up time per batch.
- Safety & Sustainability: Lower exposure to hazardous solvents; minimized waste and environmental impact.
- Regulatory Readiness: 21 CFR Part 11 compliant software with audit trails and controlled workflows aligned to USP/BP/EP.
- Analyst Productivity: Repetitive manual steps eliminated; analysts focus on investigation and data review.

Analyst Experience with ePrep ONE

The intuitive interface, guided workflows and pre-set method templates reduce training time and enable consistent execution. Automated syringe mixing improves on manual shaking to produce higher extraction surface area for improved and highly reproducible analyte partitioning. While sealed vial extractions reduce odour and exposure. Built-in blanks/standards and auto-transfer to autosampler vials streamline end-to-end preparation.

"Automation with ePrep ONE has transformed our workflow by enhancing precision, ensuring compliance, and promoting sustainability - all while saving valuable time and resources." Helen Evans-Lemmo, Ego Pharmaceuticals

Conclusion

By adopting ePrep ONE automation, Ego Pharmaceuticals achieved a validated, efficient and sustainable solution for PAH testing in liquid paraffin - setting a new benchmark for laboratory productivity and compliance. The approach is scalable to other liquid matrices, offering future-proof flexibility for evolving method requirements.

For more in-depth detail, please contact us at sales@eprep.com.au or your local distributor for ePrep Publication 98-35044AP.