

MONITORING OF LEACHABLE COMPOUNDS IN HOSPITAL PHARMACY-COMPOUNDED DRUG PRODUCTS BY UHPLC-HRMS

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Introduction

- Hospital pharmacy-compounded drug products are crucial for patient care because they are time- and cost-effective in hospital pharmacy settings, i.e., they prevent waste, preparation, and dosage errors at patient's bedsides, ensuring microbiological integrity and increases care givers security.
- The drawback of this approach included the risk of selecting unsuitable storage containers. Indeed, plastic material could release leachables which are of major concern regarding the toxicity and safety of the treated population exposed.

Objectives

- Establish a comprehensive leachable profiling method by UHPLC-HRMS
- Investigate hospital pharmacy compounded drug product
- Set up a toxicological risk assessment for each of the investigated compoundings.

Conclusion

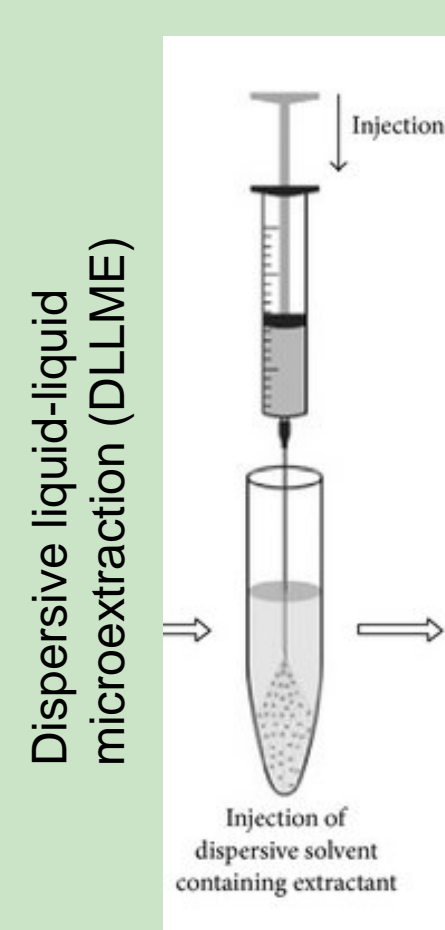
- Respectively 17, 25 and 10 leachables were identified at level 1 for the vancomycin prefilled syringe, pediatric parenteral bag and for the insulin COC vial.
- Toxicological risk was obtained by calculating the permissible daily exposure (PDE). The total daily exposure (TDE) of two compounds surpassed their estimative PDE threshold in the vancomycin prefilled syringe.
- The findings clearly highlight the optimal potential of the COC plastic material to be used in long-term storage in comparison to the inappropriate use of other MDs (prefilled-syringes and IV bag).

Methods

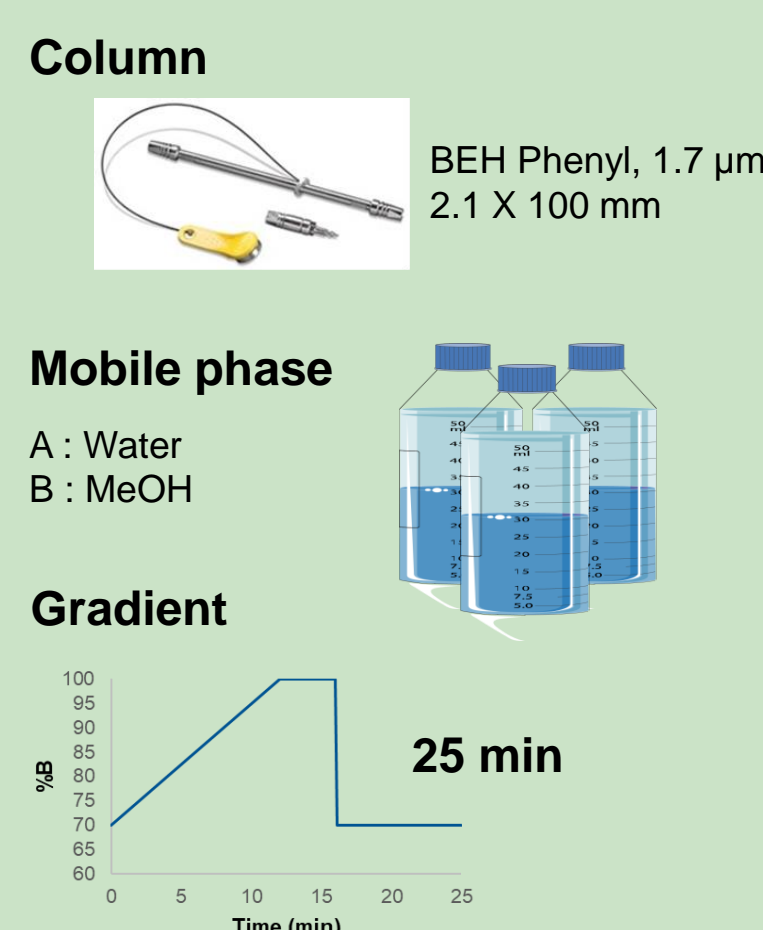
Samples investigated



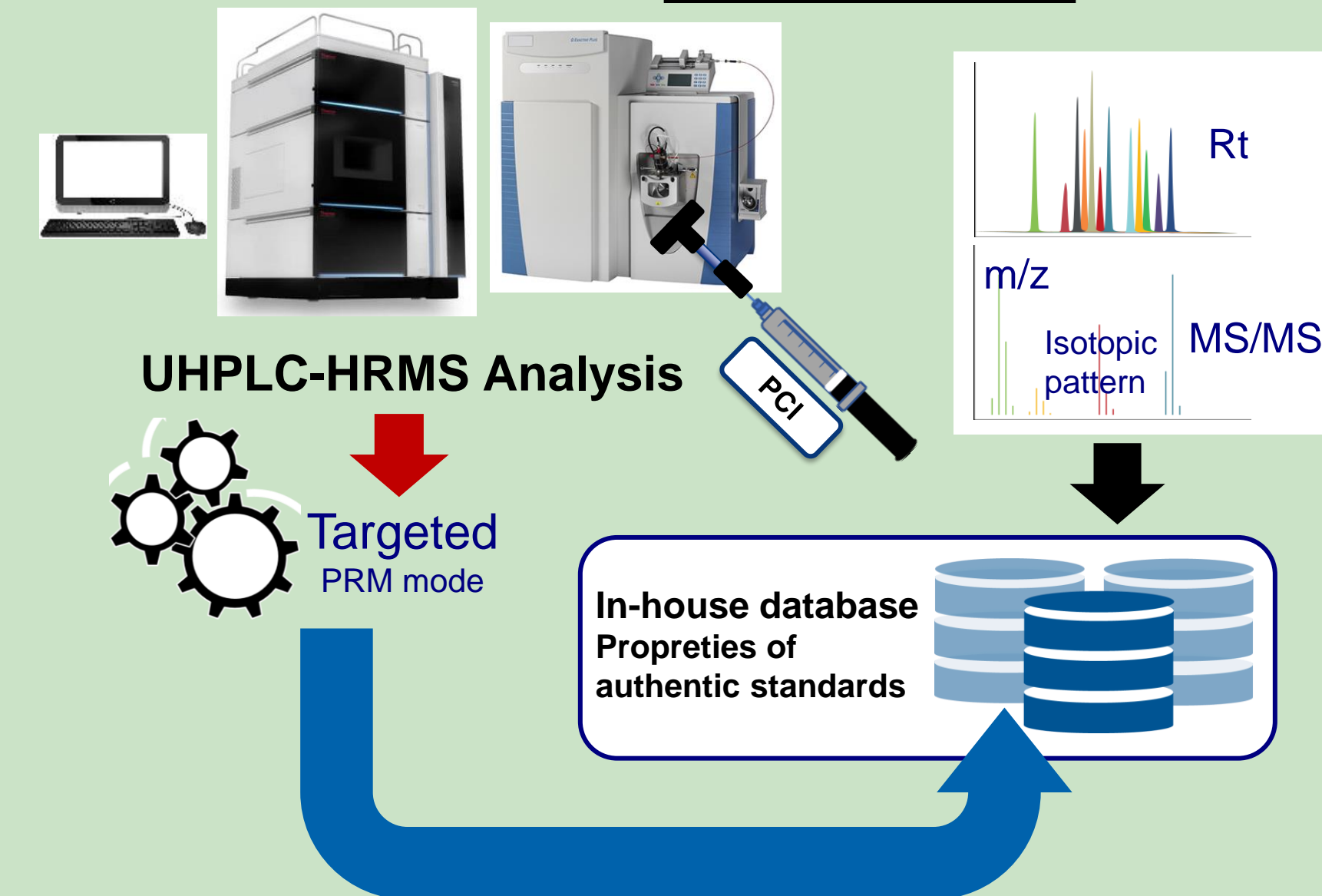
Sample preparation



LC separation

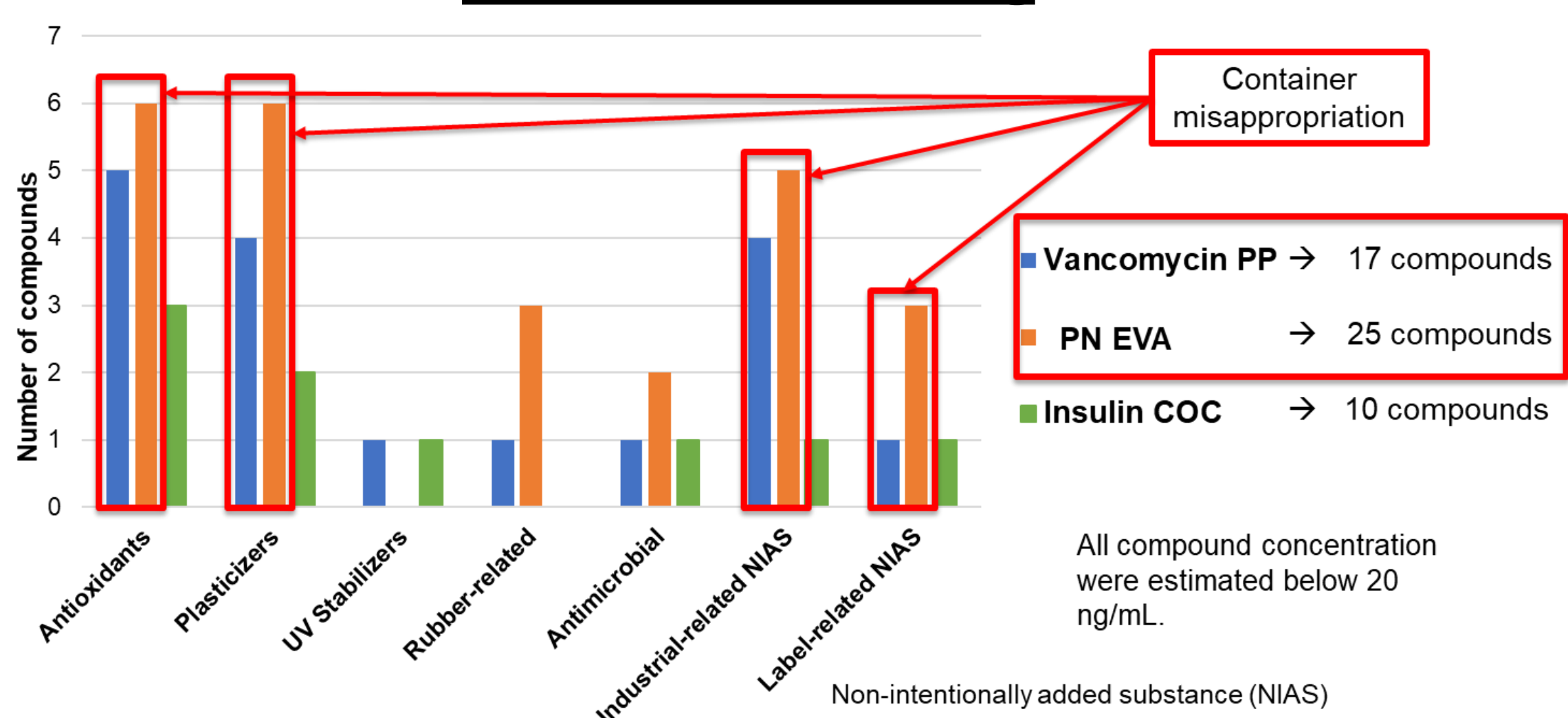


Data acquisition

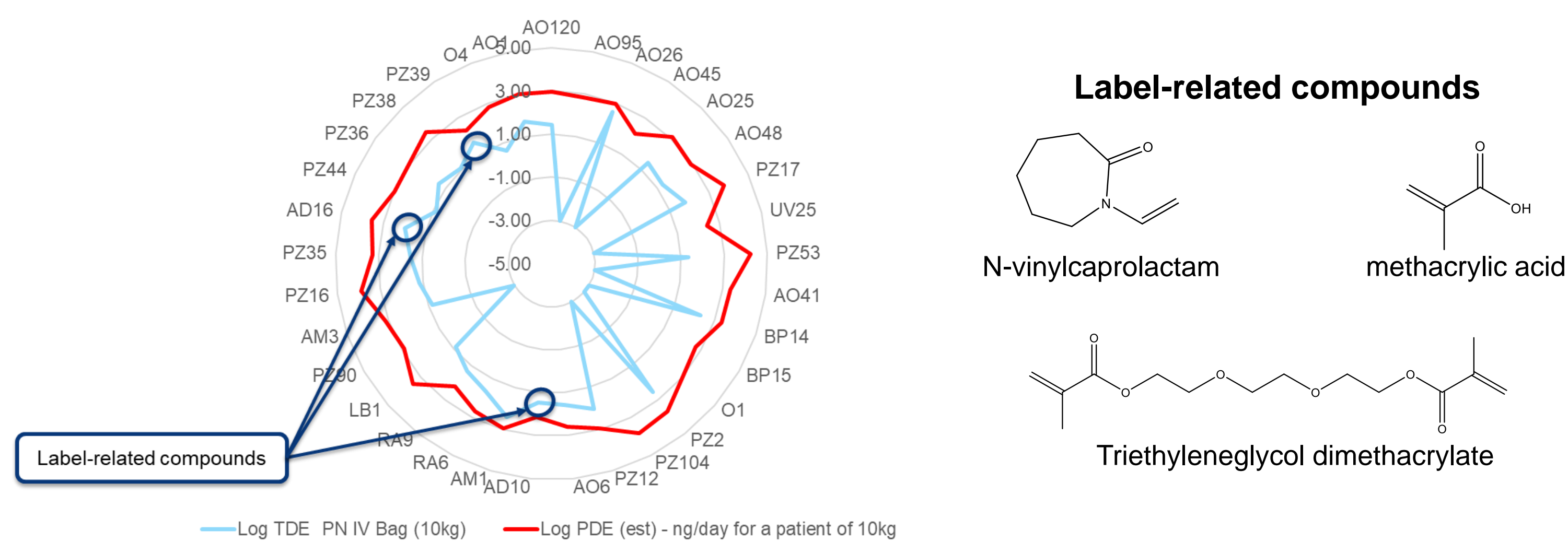


Results

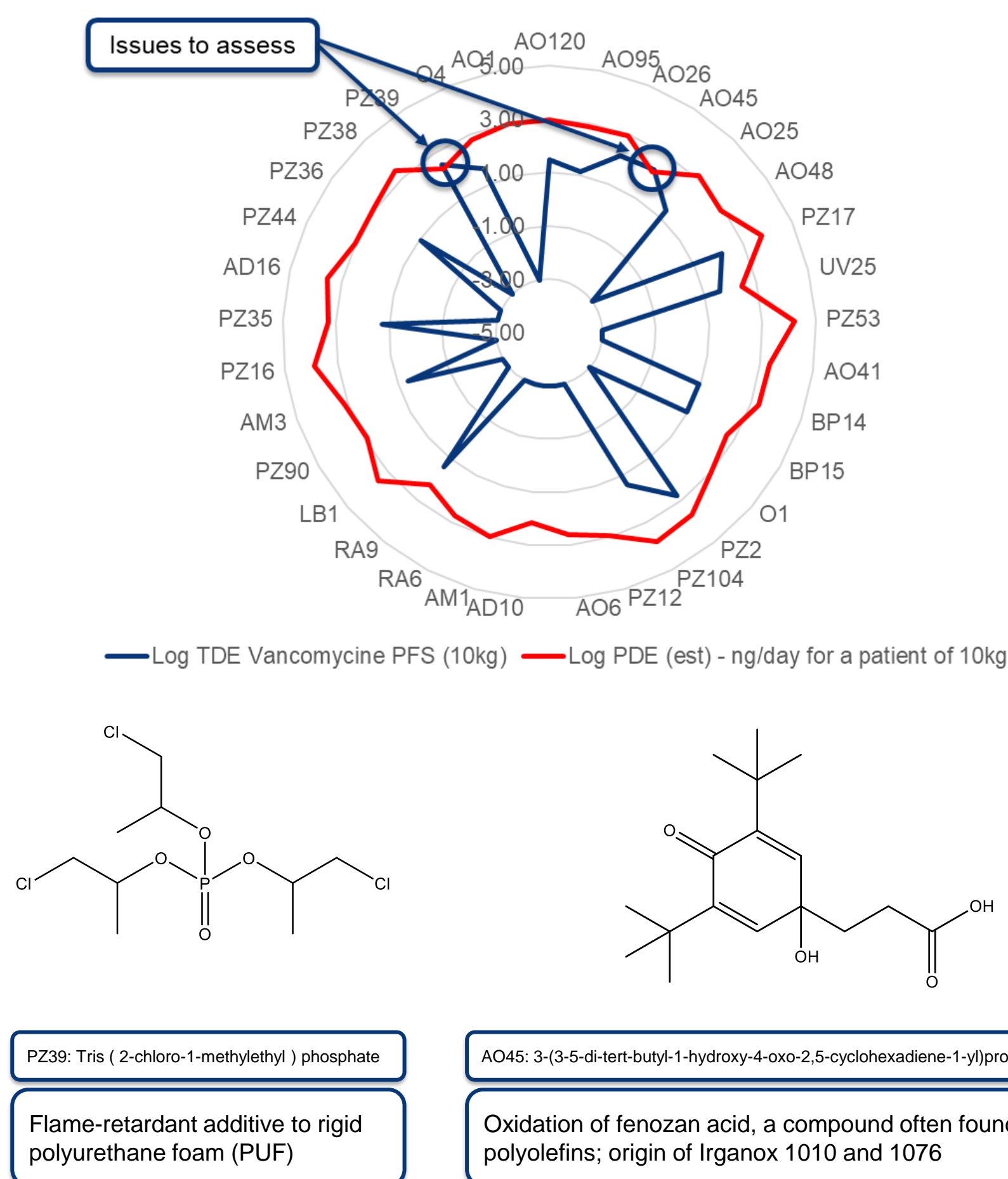
Leachables Profiling



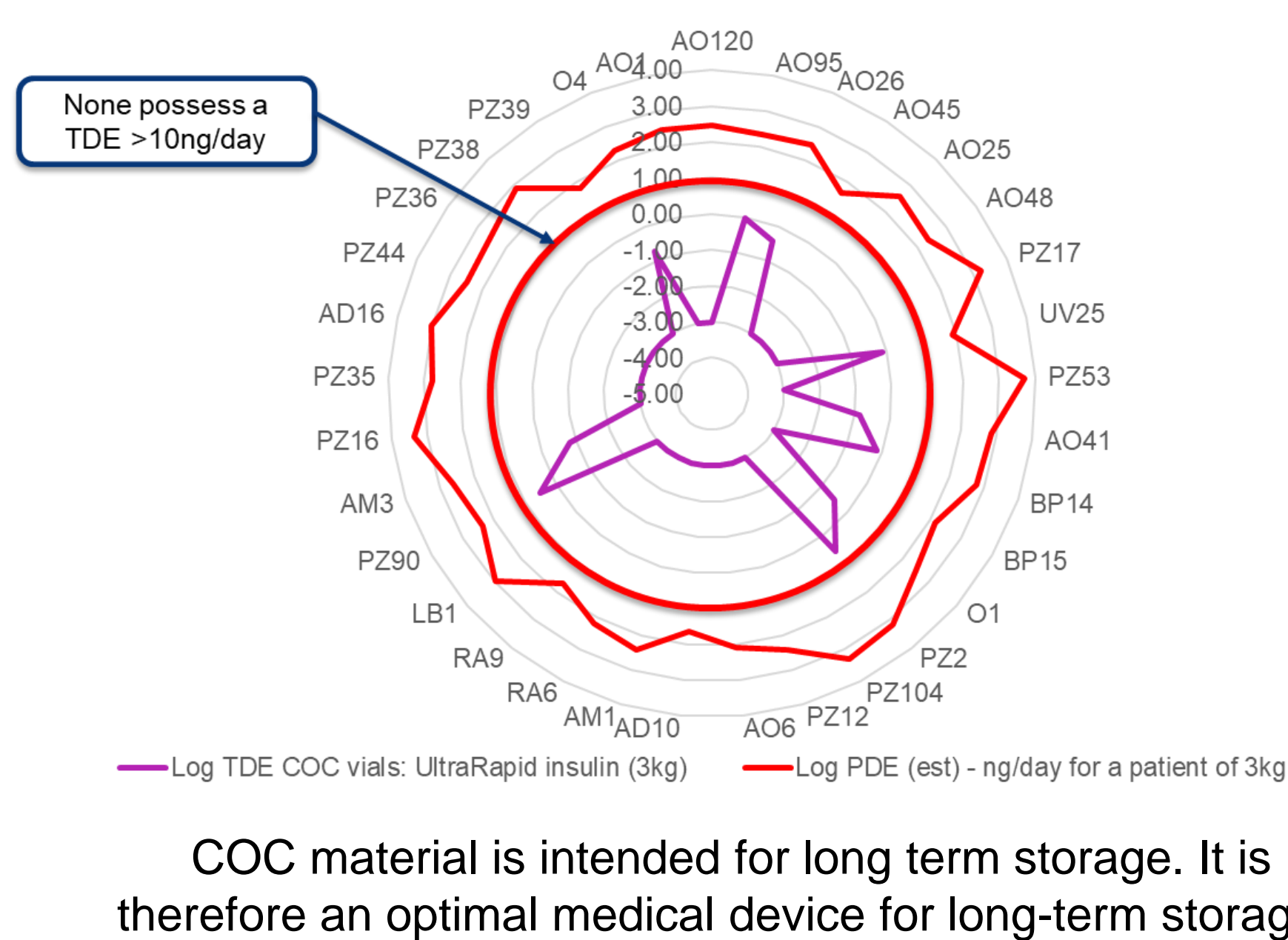
Risk Assessment 2 – Infusion Bag



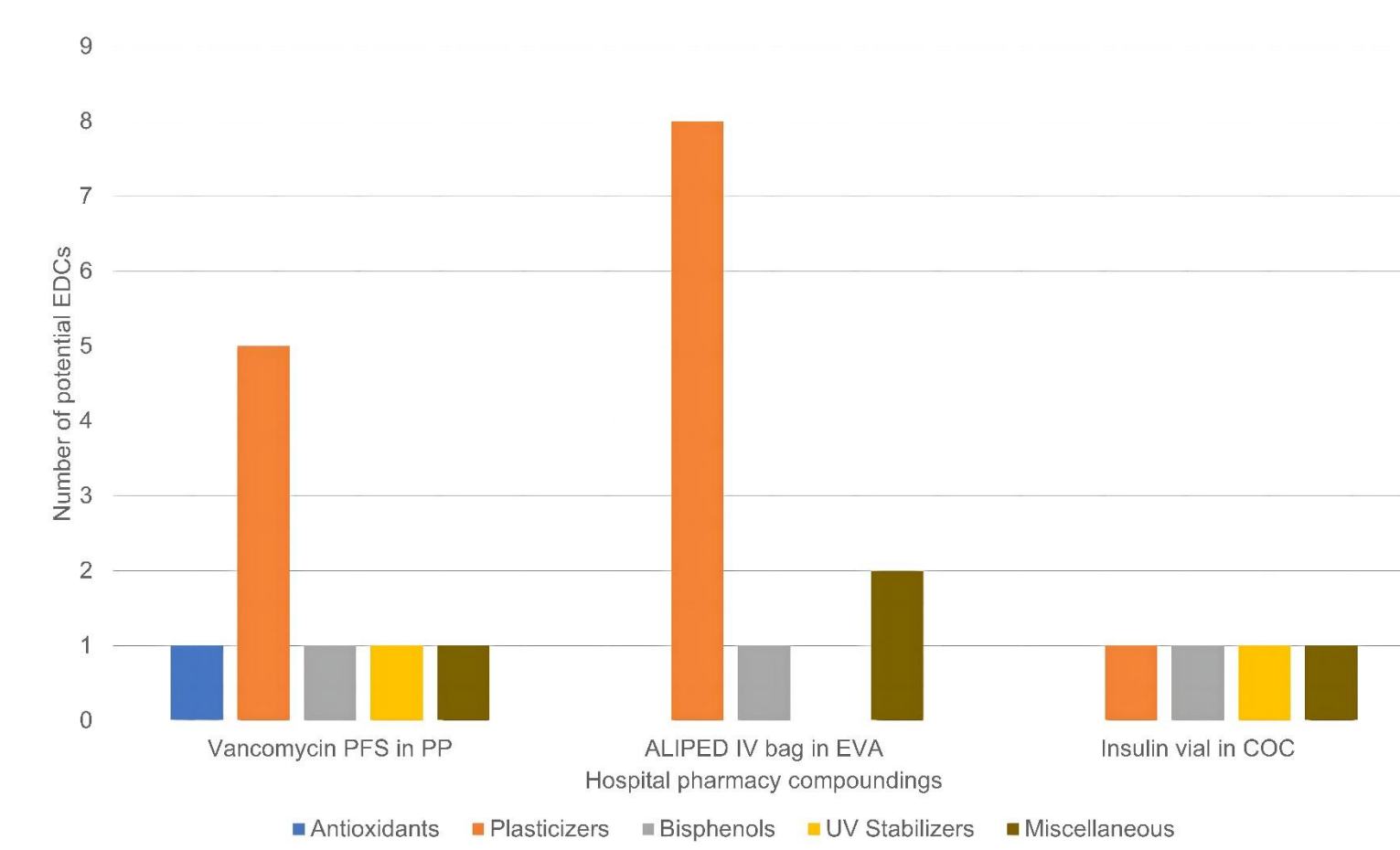
Risk Assessment 1 – Prefilled syringe



Risk Assessment 3 – COC Vial



Potential endocrine disruptors



Potential EDCs were significant in the vancomycin PFS and the PN IV bag compared to the COC vial.

TDE: Total Daily Exposure (related to the analysed compounded drug product)
PDE: Permissible Daily Exposure (related to the semi-quantified compound and the weight of the patient)