Compatibility of Thermoplastic Polyurethanes with Drugs for IV Sets

Yolanda Zhu¹, Clark Yan¹, Wei-bo Qiu¹, Hong Zhang², Elena Draganoiu³

¹Lubrizol LifeSciences, Lubrizol Specialty Chemicals Co., Ltd., Shanghai, China, ²Institute of Chemistry Research, China National Science Academy, Beijing, China, ³Lubrizol LifeSciences, Lubrizol Advanced Materials, Inc., Cleveland, OH, USA

Methodology

Compatibility between medications and intravascular (IV) administration sets is important for assuring predictable delivery of the drug dose, safety and efficacy. Potential interactions include sorption, permeation of the drug into the administration set, leaching of the set material components into the drug solution. The use of thermoplastic polyurethanes (TPU) for IV sets has seen a recent increase, however a comprehensive testing had not been conducted to evaluate their compatibility with drugs. The purpose of this study was to evaluate in vitro compatibility of IV sets of thermoplastic polyurethanes with an array of drugs with different properties.

Purpose

Materials – Three types of infusions sets (Jiangsu Suyun Medical Materials Co., Ltd., China) were tested: thermoplastic polyurethane set made from material supplied by Lubrizol Advanced Materials, Inc (USA), styrene butadiene thermoplastic elastomer set (TPE) and polyvinyl chloride (PVC) set (standard PVC with diethylhexyl phthalate). All sets had similar tube design: OD 4 mm, ID 2.4mm, length 1.6 m (Fig. 1-3).

The following commercial drugs were used in the study: Levofloxacin hydrochloride injection 100 mg/2ml (Jiangsu Ruinian Qianjin Pharmaceutical Co., Ltd., China), Metronidazole injection 500 mg/250 ml and Pantoprazole sodium for injection 40 mg (Glaxo Pharmaceutical Co., Ltd, China).

Methods – The study included seven commonly IV drugs, to cover different properties (aqueous solubility and log P) and therapeutic classes – Table 1. Commercially approved drug products were tested. The study parameters (drug dose, volume, concentration, flow rate, administration time) were designed to simulate the clinical administration (Table 1).

The concentration of drug in the solution circulated through the IV sets was quantified at different time intervals by high-performance liquid chromatography with UV detection, using reference standards. The impurity level, pH of the solution and particulates were measured at different time intervals by high-performance liquid chromatography with UV detection, using reference standards.

In the case of pantoprazole sodium, TPU IV sets performed slightly better, having lower initial sorption compared to TPE and PVC – Fig. 7.

Conclusion

TPU based IV sets performed similar or better than TPE or PVC, showing very low sorption for drug of different properties:

- Levofloxacin hydrochloride
- Moxifloxacin hydrochloride
- Metronidazole
- Docetaxel
- Furosemide
- Ranitidine hydrochloride
- Pantoprazole sodium

In the case of pantoprazole, TPU IV sets performed slightly better, having lower sorption compared to TPE (initial stage) and PVC (entire duration). The TPU properties and their compatibility with drugs, make them suitable for use in intravascular administration sets.