COLLEGE OF PHARMACY
PHARMACEUTICAL SCIENCES
UNIVERSITY OF MICHIGAN

Pharmaceutical Sciences Seminar Series

Wednesday, May 17, 2023
4:00pm
NCRC Building 10 Research Auditorium
Zoom

"The Impacts of Critical Product Attributes on In Vitro and In Vivo Performance of Onivyde"

Presented by:

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Abstract: Onivyde® is a liposomal formulation with irinotecan, approved in 2015. In addition to its high annual sales of $139.47 million, its patent exclusivity ending in 2025 makes it a lucrative target for generic competition. However, formulating generic versions of liposomal products that meet the FDA's acceptance criteria for comparability is challenging. Thus, we propose developing "Q1/Q2" irinotecan liposomal formulations to better understand how varying manufacturing conditions and product handling impact product's physicochemical properties. We aim to bridge the knowledge gaps in Onivyde® generic product development and identify critical characteristics affecting the product's in vivo performance.
In our study, we examined the size distribution of four lots of commercially available Onivyde® and found that they ranged from 108.2 nm to 112.5 nm, with irinotecan trapped inside as confirmed by Cryo-TEM. The lipid components and irinotecan concentration of these lots were consistent with their labels. We also optimized certain factors to create an in vitro drug release (IVR) assay, which successfully identified differences in stressed Onivyde®. Our final IVR assay used a 50kDa regenerated cellulose membrane in 5mM ammonium bicarbonate in HEPES (pH 7.4) at 37°C. Although we attempted to produce a liposomal formulation of irinotecan in the lab, further analysis is needed to refine our results. To further our understanding of Onivyde®, we developed a method for evaluating its in vivo performance. By applying this analysis to our in-house formulations, we hope to gain insight into how different product attributes impact in vivo performance. This information will be particularly useful for the development of generic versions of Onivyde® that meet the FDA's standards for comparability.