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Fall 10-19-2015

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Recommended Citation

Mohamad Awada, "Application of BPOG standardized extractables protocol to container films: The impact of different sample conditions and analytical procedures on E&L profile" in "Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications", Ekta Mahajan, Genentech, Inc., USA Gary Lye, University College London, UK Eds, ECI Symposium Series, (2015). <http://dc.engconfintl.org/biopoly/10>

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Application of BPOG Standardized Extractables Protocol to Container Films: The Impact of Different Sample Conditions and Analytical Procedures on E&L Profile

The E&L profile of Single-Use-Systems (SUS) include base polymers, additives, processing aids, and degradants that could potentially migrate from the container materials to contact solvents. Different conditions (such as temperature, surface area to volume ratio, dynamic/static incubation, and solvents) could produce different E&L profiles. In order to mitigate this problem, the BPOG Extractables Work Group has recently published a standardized extractables protocol recommendation in the form of a white paper (1) that defines sample conditions and analytical procedures for extractable testing.

This presentation will discuss the E&L container film results of an ongoing study performed following BPOG guidelines compared to the results of previous studies performed under vastly different conditions.

1 Ding W, et al. Standardized Extractables Testing Protocol for Single-Use Systems in Biomanufacturing. *Pharmaceut. Eng.* 34(6) 2014.