

Fall 10-20-2015

Monitoring clearance of extractables and leachables from Single-Use Technologies by NMR

Nicholas Margarian
Genentech Inc, magarian@gene.com

Kate Lee
Genentech Inc

Kunal Nagpal
Genentech Inc

Ken Skidmore
Genentech Inc

Follow this and additional works at: <http://dc.engconfintl.org/biopoly>

 Part of the [Materials Science and Engineering Commons](#)

Recommended Citation

Nicholas Margarian, Kate Lee, Kunal Nagpal, and Ken Skidmore, "Monitoring clearance of extractables and leachables from Single-Use Technologies by NMR" 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/34>

This Conference Proceeding is brought to you for free and open access by the Proceedings at ECI Digital Archives. It has been accepted for inclusion in Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications by an authorized administrator of ECI Digital Archives. For more information, please contact franco@bepress.com.

MONITORING CLEARANCE OF EXTRACTABLES AND LEACHABLES FROM SINGLE-USE TECHNOLOGIES BY NMR

Nicholas Magarian, Genentech, Inc.
magarian@gene.com
Kate Lee, Genentech, Inc.
Kunal Nagpal, Genentech, Inc.
Ken Skidmore, Genentech, Inc.

Key Words: Quantitative NMR, Single-Use Technologies, Ultrafiltration/Diafiltration, Extractables and Leachables, Process impurity testing

Process validation at Genentech requires NMR methods capable of detecting and reliably quantifying trace levels of process impurities and leachables. Measurements must be done in solutions which are far from ideal for NMR. Depending on the application, high protein and buffer concentrations, along with the presence of water, necessitate an approach to NMR measurements and data interpretation which differs greatly from traditional NMR methods. Here, we show how we deal with these complications, and how our methods may be applied to measuring the concentrations of leachables from single-use products.