

WHAT ARE GELS AND HOW TO REDUCE THEM

Xueyuan Wang, Bayer
xueyuan.wang@bayer.com
Russell Wong, Bayer

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Gels are a common quality problem in plastic films. Gel formation in polyolefin film is a phenomenon that is difficult to predict, reproduce and solve. 1 Gels are not only an aesthetic concern, but also could affect bag integrity and raise concerns of extractables/leachables in biopharmaceutical industry. Gels could be caused by un-melted resins, cross linked/oxidized polymers, additives, air bubbles, moisture and foreign contaminants. It is important to identify the root cause of gels and take appropriate actions to reduce them. If the wrong counteraction is applied, the problem can intensify.

Currently, biopharmaceutical industry lacks a standard for particle/black spec specification in single-use systems. This presentation overviews the mechanism of gels, how process conditions and screw designs affect gel formation and strategies to reduce gels. Gel identification techniques and acceptance standards used in other industries are discussed.

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