

Incorporating Potential Environmental Impact from Water for Injection in Environmental Assessment of Monoclonal Antibody Production

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ABSTRACT

Biopharmaceutical industries consistently demand Water for Injection (WFI) in their production. WFI production requires large amount of energy that may leave environmental footprint. However, its potential environmental impact (PEI) is typically not included in environmental assessment. This paper aims to present how WFI generation would contribute to environmental pollution. It was assumed that WFI was generated in Multiple Effect Distillation (MED), where utility steam is used as heating media. Utility steam is generated in a steam boiler, where several gas pollutants are produced as by-product. The PEI of these pollutants was estimated based on a modified Waste Reduction (WAR) Algorithm. For data generation, MED was simulated in SuperPro Designer®. To demonstrate the way to include WFI into an environmental assessment, a hypothetical monoclonal antibody process was used as a case-study. From the case-study, it can be seen that WFI generation contributed the most to energy consumption and to the total PEI value. Therefore, it is important to include PEI from WFI in the environmental assessment for more accurate results, particularly when comparing several process designs as the results may influence decision-making.

KEYWORDS: Environmental assessment; potential environmental impact; Multiple Effect Distillation; monoclonal antibody production; WAR algorithm

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