

EXTRACTABLES STUDIES ON SINGLE-USE COMPONENTS IN THE MANUFACTURE OF ANTIBODY DRUG CONJUGATES (ADCs)

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Antibody drug conjugates (ADC) is a class of biotherapeutic molecules that are rapidly growing in numbers with at least two products on the market and multiple in clinical trials.

The health and safety risks of the cytotoxic drugs commonly used in ADCs are so high that it creates unique challenges for their manufacturing, specifically the containment of the coupling reactions but also subsequent removal of uncoupled drug and unwanted product variants. This type of production is a prime example for when a disposable “closed-system” approach can offer advantages. Elimination of cross-contamination between batches, avoidance of large amount of toxic waste from the cleaning process, and minimization of the exposure to operators to the toxic drugs are particularly appealing to the manufacturer of ADC's.

In ADC manufacturing processes, solvents such as DMSO (dimethyl sulfoxide) and DMA (dimethylacetamide) are often used. The compatibility between the process fluids and the plastic/ elastomeric materials used to fabricate single-use components is clearly critical and needs to be assessed. An approach to the assessment of chemical compatibility and the outcome of a model solvent extractables study addressing the disposable parts that are exposed to chemicals and reaction solutions will be presented.