



Biopharmaceutical Residual Process Impurities

Process-related impurities can occur at a variety of stages during the manufacturing process of biopharmaceuticals. These impurities may originate from upstream processes (e.g. cell and culture growth and harvest), downstream processes, or from the use of single-use technologies. Process-related impurities may include antibiotics, buffer components, surfactants, catalysts, cell-derived impurities, anti-foaming agents, process enhancing agents or compounds that leach from contact materials.

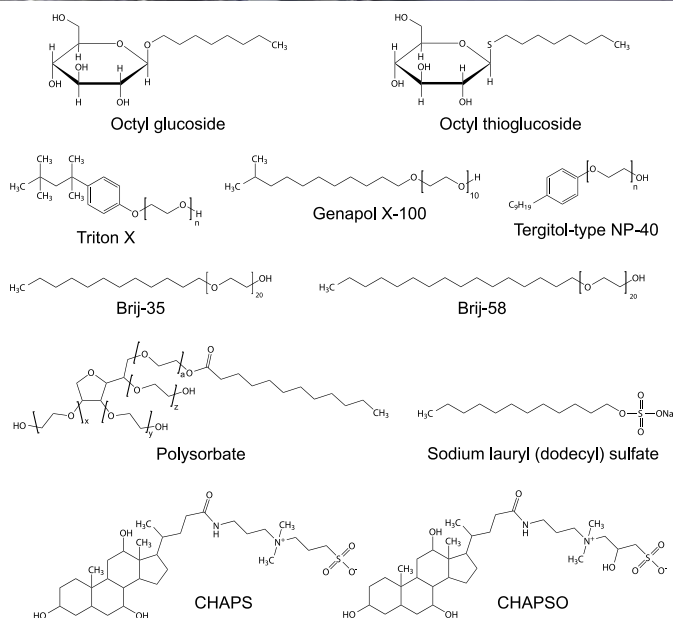
CENTRE OF
EXCELLENCE

IMPURITY AND
CONTAMINATION

Our Impurity and Contamination Centre of Excellence are experts in the identification and quantification of trace impurities in a wide range of materials used throughout the global pharmaceutical and healthcare sectors.

Detection and quantitation can be challenging as process-related impurities are usually present at low concentrations, and can be in complex matrices. Demonstration of their effective removal, or control, following manufacturing is critical to validating the manufacturing process. Biopharmaceutical process validation studies typically require a wide ranging set of testing capabilities and expertise.

We have extensive method development experience using a wide range of state-of-the-art chromatography and mass spectrometry instrumentation. These instruments are used in the development and optimisation of analytical methodology for the analysis of process related impurities to support bioprocess validation, in line with ICH Q6B.





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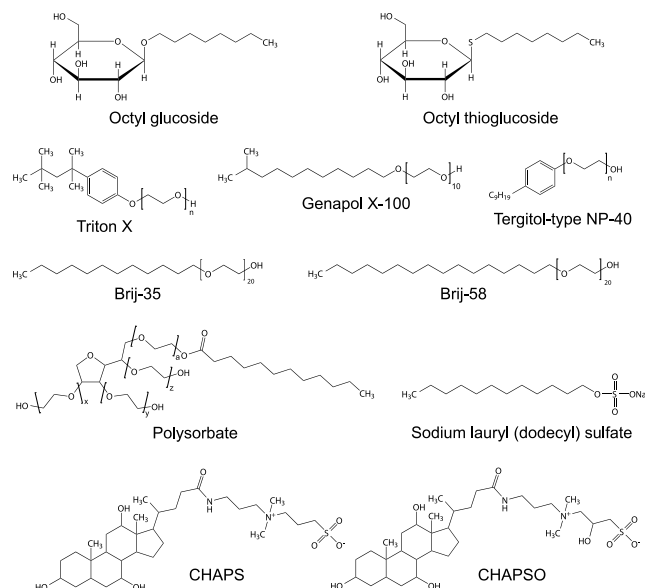
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Techniques

- » HPLC and UPLC with PDA, MS, UV
- » GC and Headspace GC with FID, ECD, MS (Agilent 7890B GC with Agilent 5977 MSD)
- » High resolution LC-MS
 - Waters Acquity H-Class (PDA) with Waters Synapt G2 Q-TOF MS (with Ion Mobility Separation)
 - Waters Acquity H-Class (PDA) with Waters Xevo G2 XS MS
- » Supercritical fluid chromatography (SFC) PDA, MS
- » Inductively Coupled Plasma with Optical Emission Spectrometry (ICP-OES) - Thermo iCAP7600 Duo
- » Inductively Coupled Plasma with Mass Spectrometry (ICP-MS) - Agilent 7700x and Agilent 7900

We can develop methods for the following types of potential impurities listed below, covering all stages of the manufacturing process:

- » Antifoams
- » Antibiotics
- » Growth Promoters
- » Redox Reagents
- » Detergents
- » Process Additives
- » Extractables and Leachables

The optimised methods can then be validated either as a limit test or full ICH Q2(R1) validation, all performed at our GMP Laboratories.



Let's discuss your project:
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