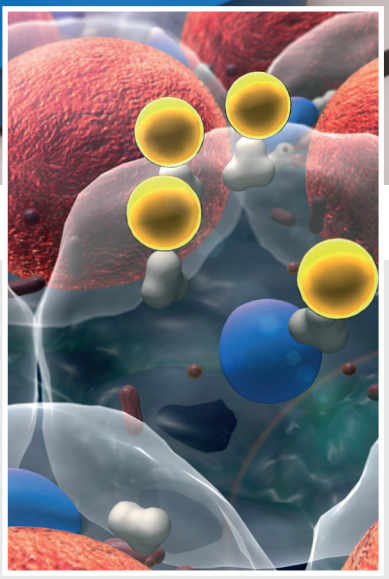
Process and Product Related Impurity Analysis



Regulatory guidance ICH Q6B and EMA set out a framework of guidelines for controlling the impurities of your biopharmaceutical product. These impurities can be classified as process or product related. Process related impurities are derived from the manufacturing process e.g. cell culture, downstream or cell substrates and product related impurities are molecular variants of the biologic which are formed during expression, manufacture or storage. Understanding these impurities in your product is an essential first step in devising control strategies to reduce or remove them.

Reading Scientific Services Ltd
The Reading Science Centre, Whiteknights Campus, Pepper Lane, Reading, Berkshire RG6 6LA
Tel: **+44 (0)118 918 4076** Email: **enquiries@rssl.com** Web: **www.rssl.com**

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RSSL's Protein Analytical Services

RSSL offers a comprehensive range of analytical services around the identification and quantification of impurities as required in ICH Q6B and EMA Guidelines. These methods can be validated as per your requirements and applied in process validation or product release.

PROCESS RELATED IMPURITIES

Cell Culture Impurities:

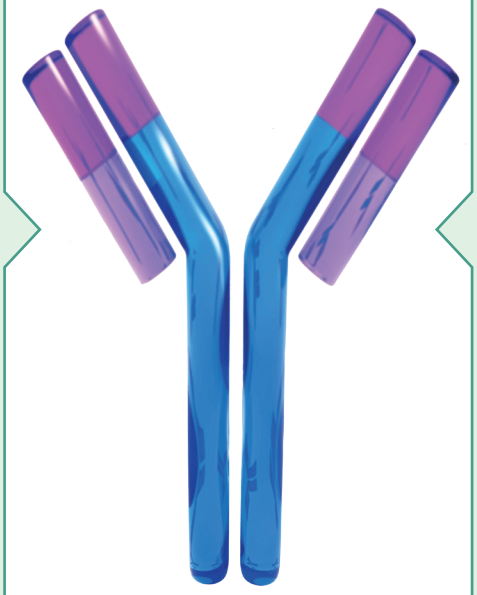
- Antifoam
- Growth Modifiers (Insulin)
- Antibiotics
- Protein A
- Solubilisers
- Residual Solvents
- Chelating Agents
- Extractables and Leachables

Cell Derived:

- Host Cell DNA and Protein

Downstream Derived:

- Detergent
- Protein A
- Process Additives
- Chromatographic Resins
- Extractables and Leachables



PRODUCT RELATED IMPURITIES

Truncated Forms:

- Truncation
- Fragmentation

Modified Forms:

- Di-sulfide Analysis
- Oxidation/Deamidation
- Glycosylation

Aggregates:

- Multimers
- Aggregates
- Subvisible Particulates

Additional Product Support

We offer a wide range of services to help you navigate your biopharmaceutical challenges, providing analysis to GMP, expert consultancy advice and training to support you through the development, production and quality assurance cycle.

- Protein Purification
- Method Development and Validation
- Microbiology
- Physical and Structural Characterisation
- ICH Stability Storage
- Raw Material and Finished Product Testing
- Pharmacopoeial support: BP, USP, EP, JP, CP
- Formulation Support
- Sub-visible Particle Analysis
- Biotechnology Issues Training

Contact us to find out more about our expertise and how we can support you:

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