RESIDUAL IMPURITIES

IN PHARMACEUTICAL & BIOPHARMACEUTICAL PRODUCTS

SGS has a wide range of state-of-the-art chromatography and mass spectrometry instrumentation, together with extensive method development experience which are utilized in the optimization of analytical method for the analysis of impurities. The optimized method can then be validated either as a limit test or full ICH Q2(R1) validation performed under GMP.

SGS has developed methods for the analysis of the impurities listed below:

UPSTREAM FERMENTATION:	**POTENTIAL RESIDUES**
Antibiotics to control bacterial contamination or plasmid selectivity	Neomycin, Tobramycin, Kanamycin, Ampicillin, Penicillin, Amphotericin B, Tetracycline, Gentamicin Sulphate, Hygromycin B, Plasmocin, Chloramphenicol
Antifoams	Pluronics, Antifoam A,B and C, TnBP, Mazu, Struktol
Growth promoter/expresser	Insulin, IPTG
THROUGHOUT PROCESS:	
Solubilization of fermentation output	Guanidine, Urea
Redox reagents	Glutathione(G-S S-G), Dithiothreitol (DTT) Tris(2-carboxyethyl)phosphine (TCEP), Copper
Extractables and Leachables from valves tubing and storage vessels	Metals, Volatiles, Plasticisers , Antioxidants, Detergents, Oligomers and Polymers
DOWNSTREAM PROCESSING:	
Detergents	Polysorbate (Tween 20 and 80), Triton X
Process additives	PEG, PPG
Chromatographic purification agents	Resin ligands, Nickel, Imidazole, Residual Solvents

This is not an exhaustive list, SGS has methods for many other residuals, and new methods can be developed upon request.

SGS

At any stage in the process the formulation will be in contact with tubing, seals, filters, and storage containers any of which may contribute leachables to the formulation. Typically these may include plasticisers, phthalates, fatty acids and antioxidants from polymeric materials or metals from storage containers. The concentrations of these leachables can increase as the manufacturing process is repeated because of the harsh solvents and high temperatures involved. SGS also offers a comprehensive analytical program for the analysis of extractables from container/ closure systems and process equipment.

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WHEN YOU NEED TO BE SURE