ANTIBODY-DRUG CONJUGATE (ADC) ANALYSIS

IN ACCORDANCE WITH REGULATORY GUIDELINES

Antibody-drug conjugates (ADCs) represent a new class of biopharmaceutical products with numerous products being developed for targeted cancer treatment. These products usually consist of an IgG1 or IgG4 monoclonal antibody, covalently conjugated to a drug via a linker. The antibody portion provides specificity of action, recognizes and binds to a target (cancer) cell. Consequently, the complex is internalised and the cytotoxic drug is released to kill the cancer cell.

SGS offers full structural characterization, physico-chemical testing and biophysical analysis of the monoclonal antibody intermediate and the antibody drug conjugate alongside assays for analysis of biological activity, stability studies and biopharmaceutical product formulation.

Concurrent with chemical changes to the parent protein, biophysical changes may occur as the drug load changes the hydrophobic/hydrophilic balance of the protein. These changes, in addition to the standard characterization tests for the monoclonal antibody intermediate, require the following analyses:

BIOCHEMICAL CHARACTERIZATION	
Conjugate ratio	Number of conjugated drug molecules and batch to batch comparability/variability
Site of conjugation	Location and comparability of site of conjugation batch to batch
Linker adducts	Unreacted linkers from conjugation chemistry
Free Drug content	Non conjugated contaminant from linker chemistry
Free Protein	Unreacted protein
BIOLOGICAL ACTIVITY	
Changes in binding site structure	Antigen Antibody Binding by Biacore or ELISA
Cell Targeting	Direction of drug action
BIOPHYSICAL CHANGES	
Secondary Structure	Scrambling or cross linking of disulfide bonds
Tertiary Structure	Alterations in beta sheet, alpha helix ratio
Aggregation	Effect of drug or linker on hydrophobic: hydrophilic patches
Stability	Conjugated drug may disrupt parent stability and the ADC may require re-formulation

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Furthermore, SGS Life Science Services is able to offer biological activity testing including ADCC, CDC and antigen binding of the conjugate, antibody API and full characterization of the drug API.

Structural analysis of the monoclonal antibody intermediate should include:

- Primary Structure
- Secondary/Tertiary Structure
- Fragments/aggregates
- Charge
- Glycosylation
- Other post translational modifications
- Antigen binding
- Biological activity as appropriate
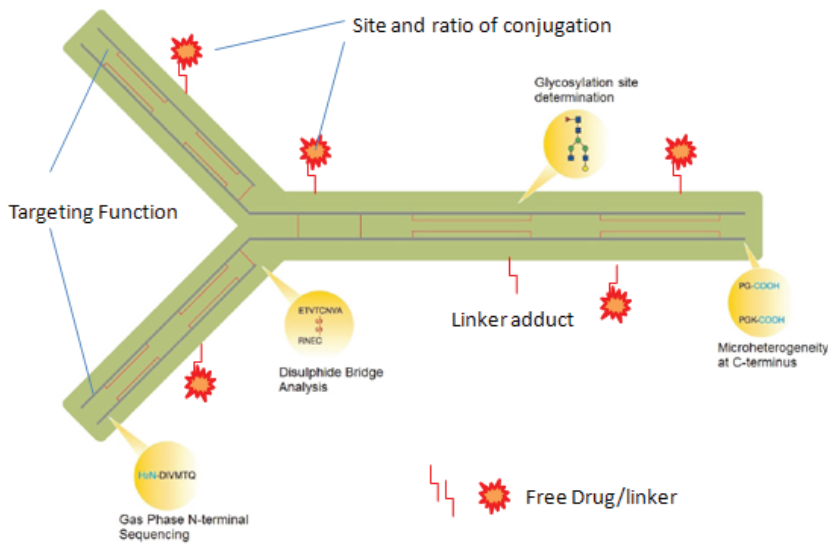
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