



Preclinical Technologies

FACTSHEET



Early Biotherapeutic Development

Safety, efficacy and mechanistic analysis at Aptuit

The cellular and biochemical mechanisms involved in biotherapeutic function are inherently complex. In depth characterization of the mechanisms of action of biotherapeutics is required to successfully support pre-clinical development to first in man. At Aptuit we have expertise in the development of biotherapeutics and biosimilars. As part of your early development program, Aptuit can provide specific support to evaluate mechanisms of action, efficacy and PK / PD assays in addition to our comprehensive range of standard safety pharmacology and toxicology studies and in vivo efficacy models.

Efficacy and mechanism of action

The efficacy and mechanism of action of biotherapeutic agents can be assessed in vitro at Aptuit using a range of cell based assays (bioassays):

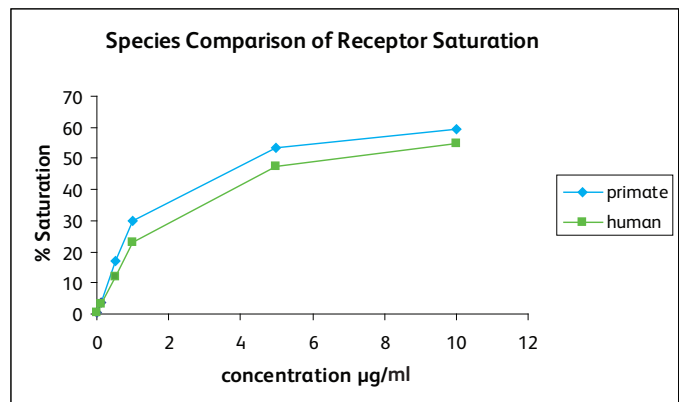
- Assays for apoptosis, proliferation and cytotoxicity (including antibody and complement dependent)
- Quantification of pharmacodynamic markers, including cytokines and pro-inflammatory mediators
- Cell signalling and enzyme activity assays
- Protein expression analysis

In addition, cellular and pharmacodynamic analysis can be carried out on samples from both ex vivo and in vivo studies.

Species selection and receptor occupancy

An important aspect of biotherapeutic development is the selection of the most appropriate species for toxicology and safety pharmacology studies. Comparison of drug binding to cell surface targets in human and the proposed toxicology species is performed using flow cytometry.

In addition, the degree of target receptor expression and percentage receptor occupancy can be established in human and non-human primary cells. Downstream signalling or activation of target receptors can also be assessed as a measure of drug potency.



Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit's services, please call or email:

+1 816 767 3900 North America

+44 131 451 2451 Europe

email: info@aptuit.com

or visit our website: www.aptuit.com

Engineering a better drug development process.