

Preclinical Safety Evaluation and Clinical Bioanalysis Services for Vaccines



Vaccine development follows a strict regulatory pathway, of which non-clinical safety assessment is a critical component. Aragen offers a spectra of preclinical research services at Intox, its fully owned subsidiary, which is an OECD GLP certified Test Facility, with a legacy of 25+ years. At Intox, we offer complete and customised non-clinical safety evaluation programs for your vaccine products, designed around the toxicological concerns that are unique to your kind of vaccine. These studies are conducted in accordance with Good Laboratory Practice (GLP). Besides, we also offer high precision bioanalytical support to your clinical trials.

End-to-End services enabling successful development of vaccines

- Product characterization
- Proof-of-concept studies
- IND supporting non-clinical efficacy / immunogenicity studies
- IND supporting non-clinical safety assessment
- Clinical sample bioanalysis

Safety studies on vaccine – Post COVID-19

(Studies performed at Intox have enabled clinical trials in India, Africa, Europe, Thailand, Australia, and several countries)

- VLP (covid-19) vaccine
- mRNA (covid-19) vaccine
- DNA (covid-19) vaccine
- Novel malaria vaccine
- Novel leishmaniasis (live) vaccine
- Novel covid-19 variant proof (multivalent) m-rna vaccine
- Immunogenicity booster studies / vaccine mixing studies

Safety studies on vaccines – Pre COVID-19

Non-recombinant vaccines

- Influenza h1n1 inactivated vaccine
- Influenza h1n1 live attenuated vaccine
- Meningitis - a conjugate vaccine
- Meningococcal polysaccharide vaccine
- Rabies vaccine inactivated, etc.

Recombinant vaccines

- Jaivac-1 (plasmodium falciparum pff2+pimspi19 formulated in montanide isa720).
- Malaria vaccine
- 10-valent pneumococcal polysaccharide conjugate vaccine
- Recombinant epsilon toxoid vaccine (veterinary product)
- Diphtheria, tetanus and acellular pertussis (dtaP) vaccines, etc.

Range of Assays and studies performed for evaluation of vaccines-under one roof

In Vitro Immune Profiling Assays for Vaccine and Adjuvants Development

- Screening peptide/antigen/live viruses
- *In vitro* immunogenicity assays
- Testing of novel adjuvants and antigen delivery vectors

In vivo potency assays and safety testing

- Hormone potency assays, such as FSH, FSH-LH, PMSG, and hCG (EP or USP)
- Vaccines, including immunopotency, immunogenicity, antisera generation, and challenge studies (bacteria/viruses)

Genetic stability studies

- Restriction endonuclease mapping
- Southern/ Northern blotting
- Copy number determination by qPCR
- DNA and RNA sequencing
- Retention of recombinant construct

In vivo biosafety testing

- Antibody production assays
- Tumorigenicity testing

Pyrogen testing

- Endotoxin Testing (LAL)
- Monocyte activation testing (MAT)
- Rabbit pyrogen test

Product Characterization & POC Studies

Offerings for Vaccines

- Identity, Titre, Mass
- Purity; Impurity analysis
- Potency; Sterility
- Binding studies – affinity, avidity; ligands per particle
- Viral clearance/ inactivation
- Genomic and virus/vector DNA sequencing
- Biomarker discovery and development
- Non-clinical safety assessment
- Immunogenicity – Humoral & Cellular
- Cytokine cascade analysis
- Bio-distribution & persistence; PK-TK

Established track record

- A preferred partner to world's largest vaccines manufacturer based out of pune since 1996.
- Supported many leading vaccine companies / programs as listed below.
 - European malaria vaccine initiative (EMVI) (Jaivac-1: A collaborative project between bharat biotech, international centre for genetic engineering and biotechnology (ICGEB) and Intox)
 - Meningitis vaccine project (MVP) - meningitis conjugate vaccine / meningococcal a conjugate vaccine - a collaborative project between PATH, Intox and Serum institute of India
 - Acellular pertussis vaccine (for a Thai-French biotech: we tested several vaccines like aP, DTaP, TdaP)
 - POC studies for vaccines (for an indian start-up)
 - Studies for qualification of a novel adjuvant, GLA-SE used for novel malaria and hepatitis B vaccine developments

