ANABIOTEC
an anacura company

From analytical data to drug development insight

“ Every solution to every problem is simple. It’s the distance between the two where the mystery lies “

- Derek Landy

Our product experience

New Chemical Entities & Generics

- Chemical entities
- Peptides
- Oligonucleotides

New Biological Entities & Biosimilars

- Monoclonal antibodies & Derivatives
- Proteins (e.g. enzymes)
- Vaccines

Cell-based Medicinal Products/ ATMPs

- Stem cells
- Car-T, NK cells
- PBMCs
- mRNA vaccines

Analytical methodology

Small Molecule Solutions

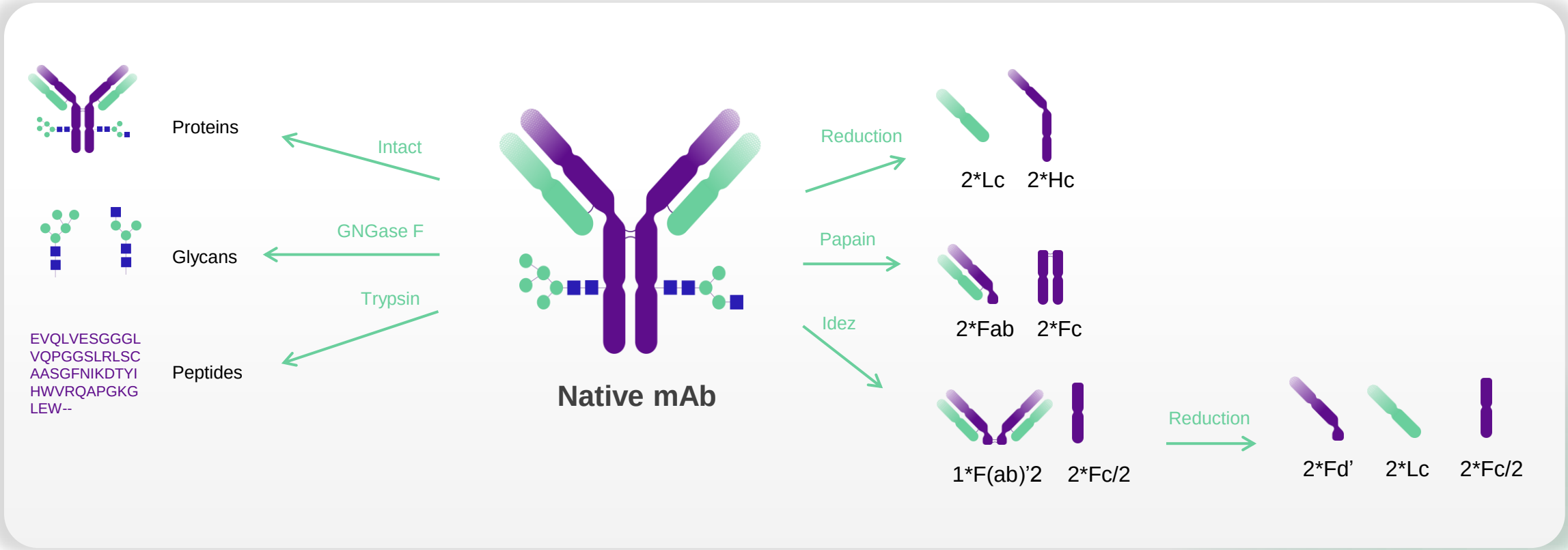
Peptides & Oligonucleotides

Product characterisation	Product attributes	Analytical method		
General quality Physicochemical	Appearance/ Clarity/ Color/ pH	Visual Inspection	Ph. Eur. 2.2.1/ Ph. Eur. 2.2.2/ Ph. Eur. 2.2.3	
	Osmolality	Osmometric	USP<785>/ Ph. Eur. 2.2.35	
	Particle contamination	Subvisible particles	Ph.Eur. 2.9.19 (method 1)	
	Extractable volume	USP<1>, Ph. Eur. 2.9.17		
	Uniformity of Dosage units	USP<905>, Ph. Eur. 2.9.40		
Identity & sequence	Identity	MS/ UV	IR	
	Sequencing	HR-MS/ MS		
Assay, purity & content	Assay/ purity	UPLC-UV	IEX-HPLC	IPRP-UV/ HPLV
	Purity/ impurity	LC-HRMS		
	Water content	KF		
	Residual solvents	GC		
	Counter ion	ICP-MS * / LC-UV		
Activity	Potency	ELISA/ Cell-based assays		

Analytical methodology

Biologics Solutions

mAb characterization

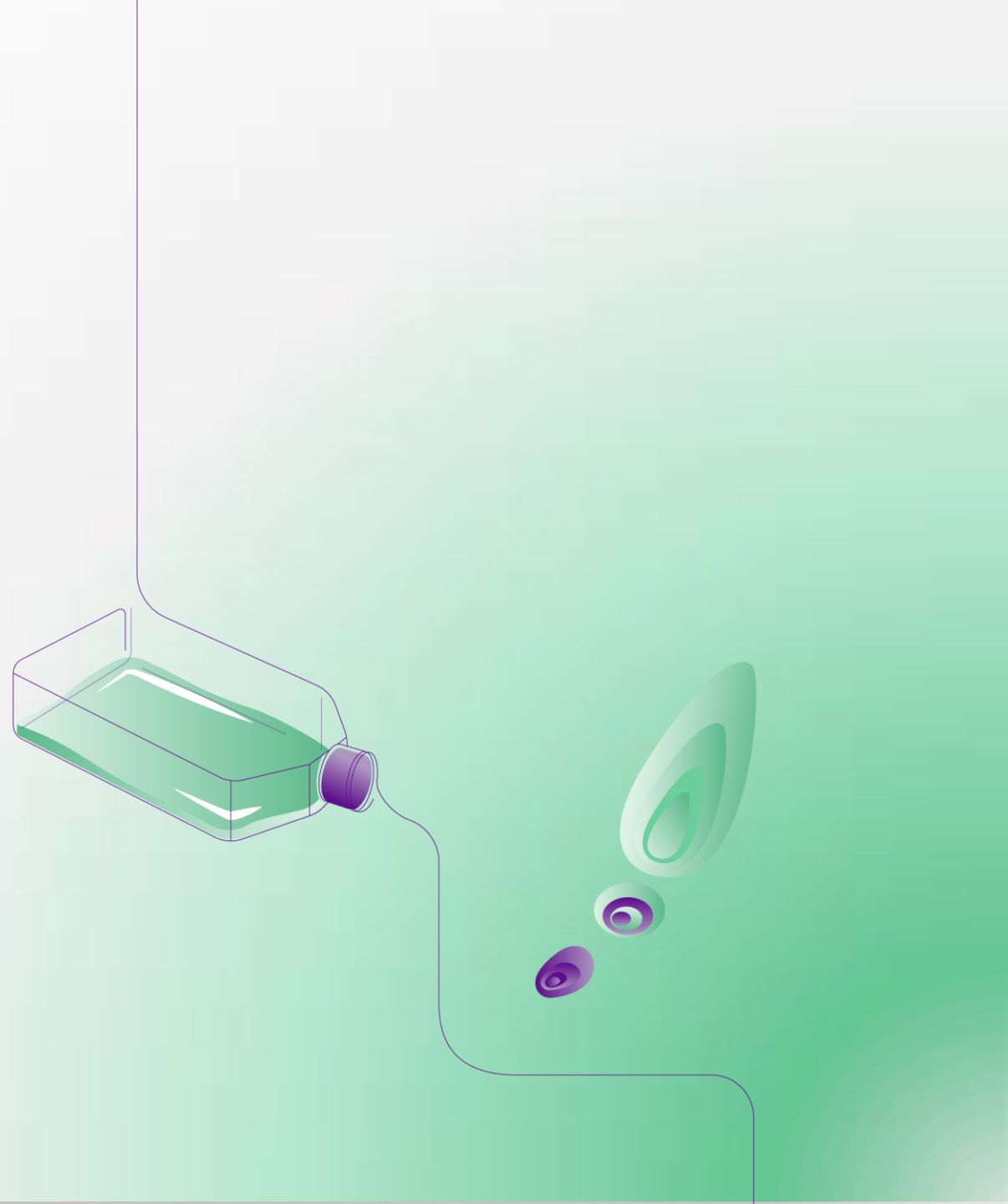


mAb characterization

Product characterisation	Product attributes	Analytical method		
General quality	Appearance/ Clarity/ Color/ pH	Visual Inspection	Ph. Eur. 2.2.1/ Ph. Eur. 2.2.2/ Ph. Eur. 2.2.3	
Protein content	Protein level	RP-(U) HPLC	MS	IEX-HPLC
	Amino acid composition	Hydrolysis FMOC/ OPA labelling		
Primary structure	Molecular weight	HRMS		
	Structural integrity	Peptide mapping		
	N-& O-glycosylation	Glycan analysis		
	N-&C-terminal sequence	Peptide mapping		LC-HRMS
Higher order	Higher order structures	Protein fragment level by LC-HRMS		
	S-S bridges	Peptide mapping (reduced, non-reduced)		
Heterogeneity	Aggregation	Particle Sizer Measurement		SECHPLC
	Charge variants	icIEF		
Post-translational modification	Deamidation/ oxidation	Peptide mapping		IEX-MS
Activity	Potency	ELISA		

Analytical methodology

Cell-based Medicinal Products



Analytical methodology - CBMP

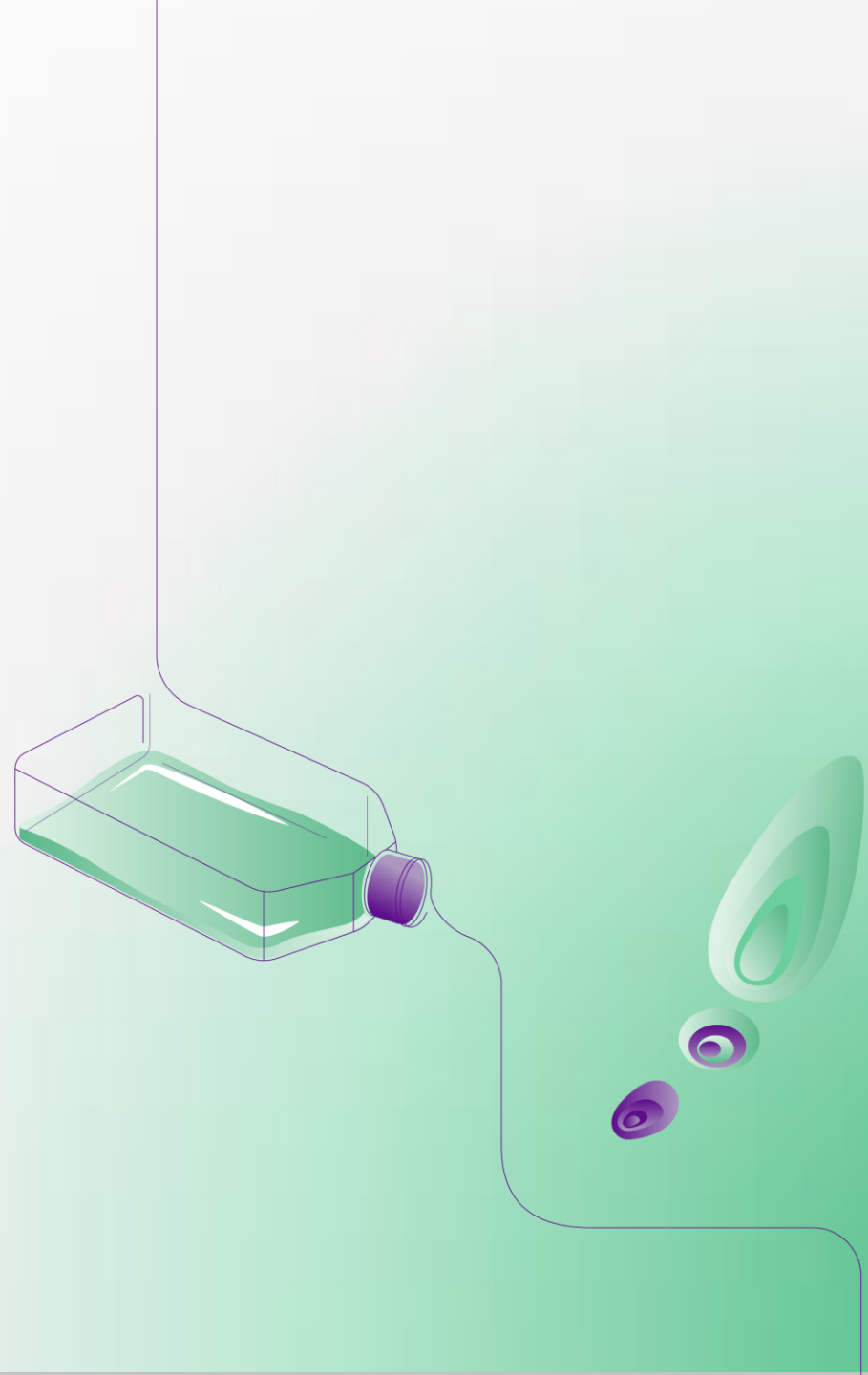
Product characterisation	Product attributes	Analytical method	
General quality Physicochemical	Appearance/ Clarity/ Color/ pH	Visual Inspection	Ph. Eur. 2.2.1/ Ph. Eur. 2.2.2/ Ph. Eur. 2.2.3
	Osmolality	Osmometric	USP<785>/ Ph. Eur. 2.2.35
	Extractable volume	USP<1> / Ph. Eur. 2.9.17	
	Particle contamination	Subvisible particles	Ph.Eur. 2.9.19 (method I)
Quantity	Cell count/ Cell viability	FACS	
	RNA/ DNA content	UV spectroscopy	
Characterization	Primer & probe design	RT-qPCR	
	Characterization	FACS/ MSD/ ELISA	
Identity	Identity	RT-qPCR/ FACS	
	Absence of markers	FACS/ ELISA	
	Gene expression	RT-qPCR	
Safety	Mycoplasma	RT-qPCR	
	VSV-G		
	Vector Copy Number		

Analytical methodology - CBMP

Product characterisation	Product attributes	Analytical method
Assay, purity & content	Expression of markers	FACS/ ELISA
	Percentage of dead cells / undesired cells	FACS
	Assay/ purity	LC-HRMS
	RNA content	UV Spectroscopy
	Purity/ impurity	LC-HRMS
	Water content	KF
	Residual solvents	GC
Potency	Biomarkers	FACS/ ELISA
	In vitro expression	Cell-based assays
	Enzymatic assays	UV spectroscopy/ Fluorescence/ Luminescence
	Gene expression	RT-qPCR

Analytical methodology

mRNA vaccines



mRNA vaccines

Product characterisation	Product attributes	Analytical method	
General quality Physicochemical	Appearance/ Clarity/ Color/ pH	Visual Inspection	Ph. Eur. 2.2.1/ Ph. Eur. 2.2.2/ Ph. Eur. 2.2.3
	Osmolality	Osmometric	USP<785>/ Ph. Eur. 2.2.35
	Extractable volume	USP<1> / Ph. Eur. 2.9.17	
	Particle contamination	Subvisible particles	Ph.Eur. 2.9.19 (method I)
Characterization	5’ Cap	LC-HRMS	
	Poly A tail	LC-HRMS	
	LNP characterization	Malvern particle sizer	
Identity & sequence	Identity	RT-qPCR	
Assay, purity & content	Assay/ purity	LC-HRMS	
	RNA content	UV Spectroscopy	
	Purity/ impurity	LC-HRMS	
	Water content	KF	
	Residual solvents	GC	

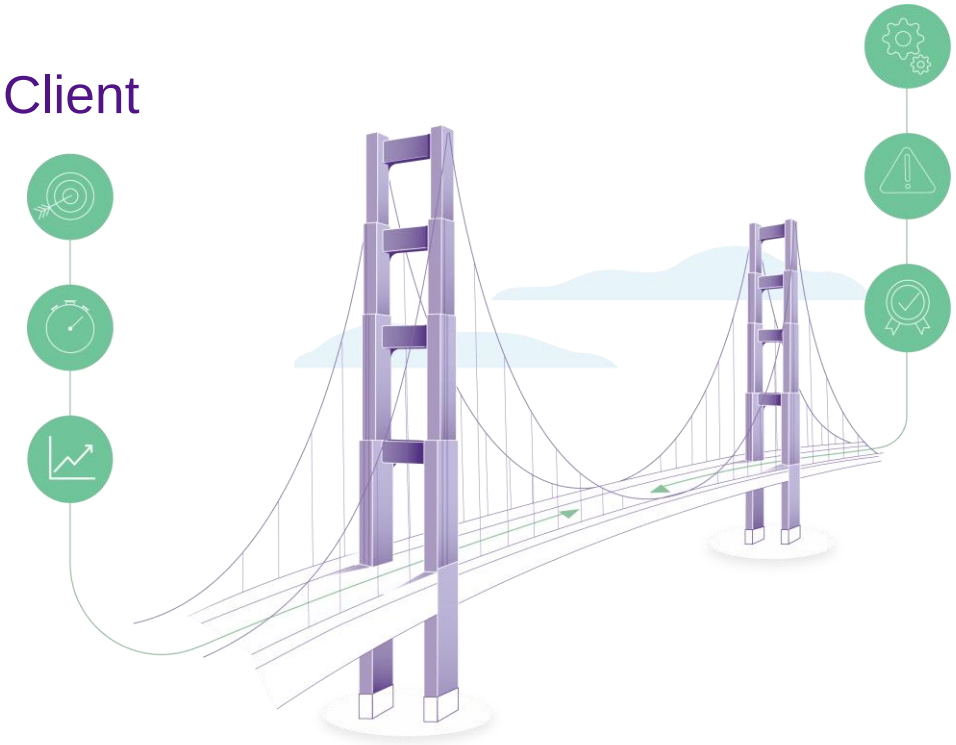
mRNA vaccines

Product characterisation	Product attributes	Analytical method
Assay, purity & content	RNA integrity	CGE
	RNA impurities	CGE
	LNP size	DLS
	LNP polydispersity	DLS
	LNA component content	HPLC-CAD
	Res HCD/ Res HCP	RT-qPCR/ ELISA
	Res dsRNA	Immunoblot
	RNA encapsulation	Fluorescence assay
Activity	Potency	In vitro expression by cell-based assays

Our approach, valued by our customers

AnaBioTec

Client



“AnaBioTec has been instrumental in the success of our program. They have developed our potency assay after our initial QC lab failed and have been running it ever since for release and stability.

Whenever I have a new project, I always consider Anabiotec for the analytics now.”

Peter Tjeerdsma, Director of CMC

Staten Biotechnology

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