

Milestone Pharma

Biologics Quality Assessment Services

submission-ready characterization for
confident glable regulatory decisions.

Founded in 2016

Empowering Clients with Science and Tech for Drug Product Launch Globally!



On-site inspection passed



Audit passed

NMPA

On-site inspection passed



Accredited laboratory

INTEGRATED ANALYTICAL SOLUTIONS

What We Do

Comprehensive characterization to understand structure, purity, stability and comparability throughout development.

01

Structural Characterization

- Peptide mapping
- Sequence and identity
- Molecular mass
- N/C-terminal analysis
- Amino acid composition
- Post-translational modifications

02

Higher-Order Structure

- CD and MMS
- FT-IR and Raman
- 1D/2D NMR
- Thermal stability

03

Aggregation & Stability

- SEC-MALS and AF4-MALS
- AUC and DLS
- Nano-DSC
- Aggregation and oligomerization

04

Impurity Profiling

- 1D/2D LC-HRMS
- Unknown peak identification
- Product-related impurities
- Process-related impurities

SUPPORTED MODALITIES

Peptides

Proteins

Antibodies

ADCs

Oligonucleotides

Vaccines

ADVANCED SCIENCE. PRACTICAL DECISIONS.

Why Clients Choose Us

A focused analytical strategy that converts complex data into clear, defensible conclusions.

01

Orthogonal Evidence

HRMS, spectroscopy, NMR, MALS and AUC

02

Regulatory-Focused Output

Clear reports designed to support CMC decisions

03

Complex Modalities

Deep expertise in GLP-1, oligonucleotides, antibodies and ADCs

04

Lifecycle Support

From method development to comparability and commercialization

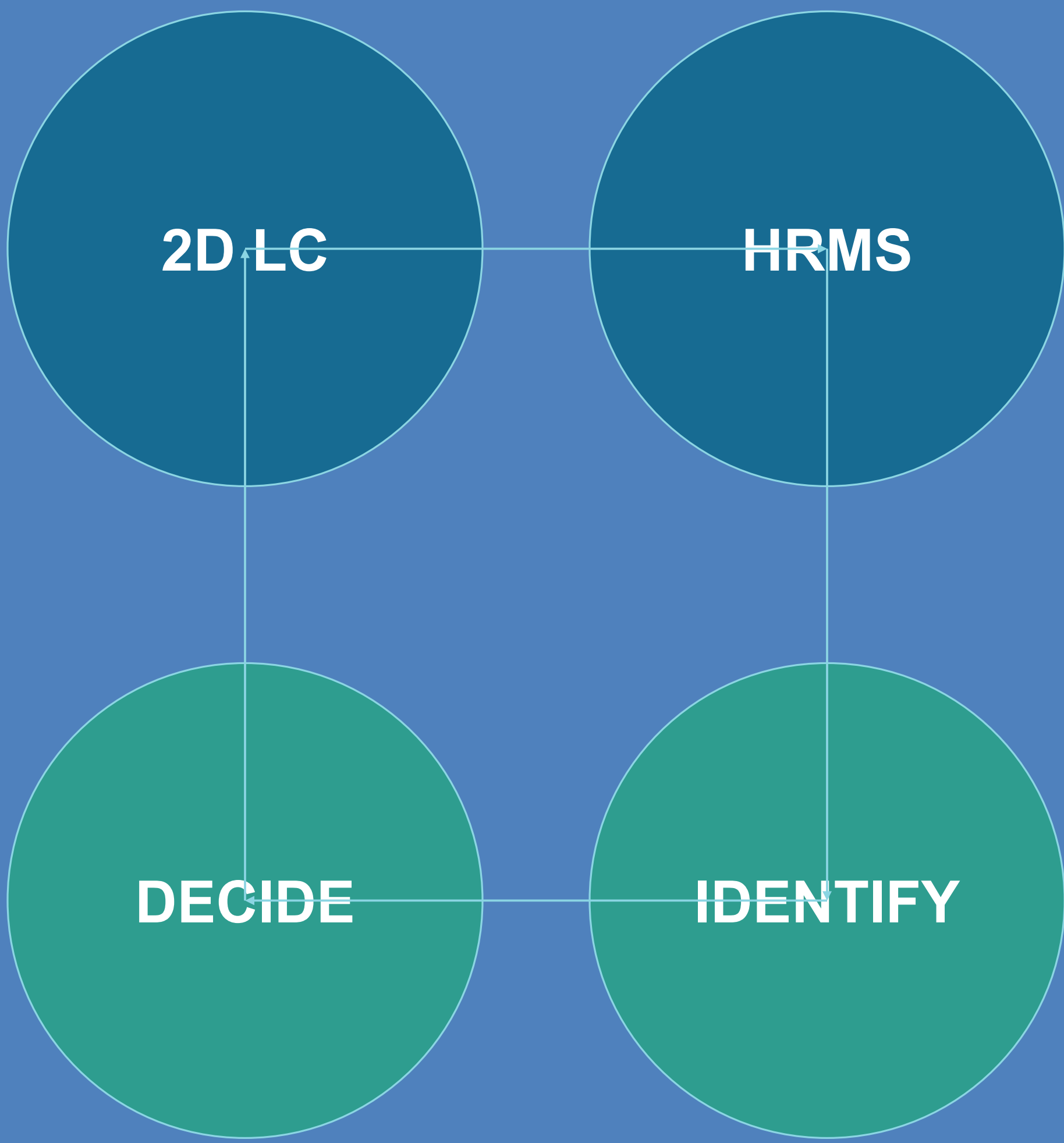
FEATURED CASE STUDY

GLP-1 Impurity Profiling by 2D LC-HRMS

CHALLENGE Trace impurity identification in complex GLP-1 products.

APPROACH Dual-oven 2D LC with multiple heart-cutting, coupled to high-resolution MS.

OUTCOME Structural elucidation to support development decisions and regulatory documentation.



From complex signals to clear decisions

A SCIENTIFIC PARTNER ACROSS THE PRODUCT LIFECYCLE

About Milestone Pharma

Integrated analytical characterization, impurity studies, comparability evaluation and regulatory support from development through commercialization.

10+

Years of Experience

330+

Scientists & Engineers

2,500+

Global Customers

10,000+

Projects Delivered

CORE INSTRUMENT PLATFORMS

HRMS

NMR

AF4-MALS

SEC-MALS

AUC

MMS

Nano-DSC

Raman

FT-IR

CD

Let's Discuss Your Next Program

www.mstonepharma.com

Marketing@mstonepharma.com



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Clear science. Confident decisions. Global support.