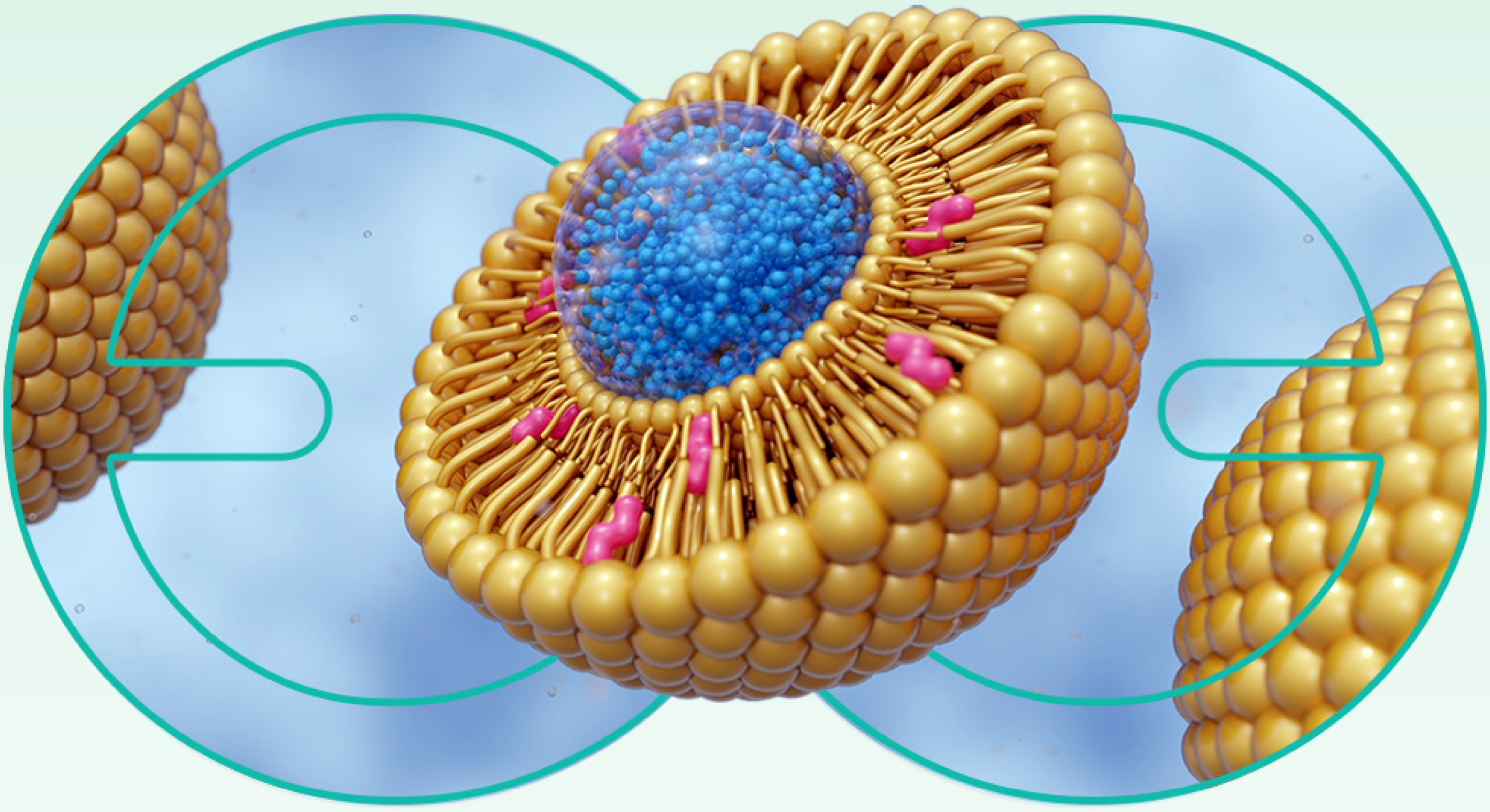
Veeda™
Lifesciences



TISSUE DISTRIBUTION OF LIPOSOMAL DRUGS:

Expertise in Complex Bioanalytical & Pharmacokinetic Studies

Background

A pharmaceutical sponsor partnered with Veeda Lifesciences to conduct a pharmacokinetic and tissue distribution study of a liposomal formulation of Amphotericin B in Sprague Dawley rats. The study was designed to support regulatory submissions to the U.S. Food and Drug Administration and European Medicines Agency.

Liposomal Amphotericin B formulations are widely used in the treatment of severe fungal infections, including Aspergillus, Candida, Cryptococcus, and visceral leishmaniasis, owing to their improved safety and biodistribution profile compared with conventional Amphotericin B formulations.

Project Scope

- Single-dose pharmacokinetic evaluation of liposomal Amphotericin B
- Tissue distribution assessment in Sprague Dawley rats
- Simultaneous quantification of:
  - Encapsulated (liposomal) Amphotericin B
  - Free (released) Amphotericin B
- Generation of a regulatory-compliant study report for global submissions

Challenges

Liposomal drug formulations present significant analytical and pharmacokinetic complexities due to:

- Differentiation between encapsulated and free drug fractions
- Stability considerations during sample handling and processing
- Sensitive quantification requirements across plasma and tissue matrices
- Regulatory expectations for robust and validated analytical methods

Veeda Lifesciences' Solution

Veeda Lifesciences developed and validated a robust LC-MS/MS bioanalytical method capable of accurately and simultaneously quantifying both liposomal and free Amphotericin B in biological matrices.

The study included:

- Single-dose pharmacokinetic evaluation in Sprague Dawley rats
- Plasma & tissue sample collection across predefined time points
- Comprehensive bioanalysis using validated LC-MS/MS methods
- Detailed pharmacokinetic and tissue distribution assessment

Our scientific team ensured method reliability, analytical sensitivity & regulatory compliance throughout the study execution.

Outcome

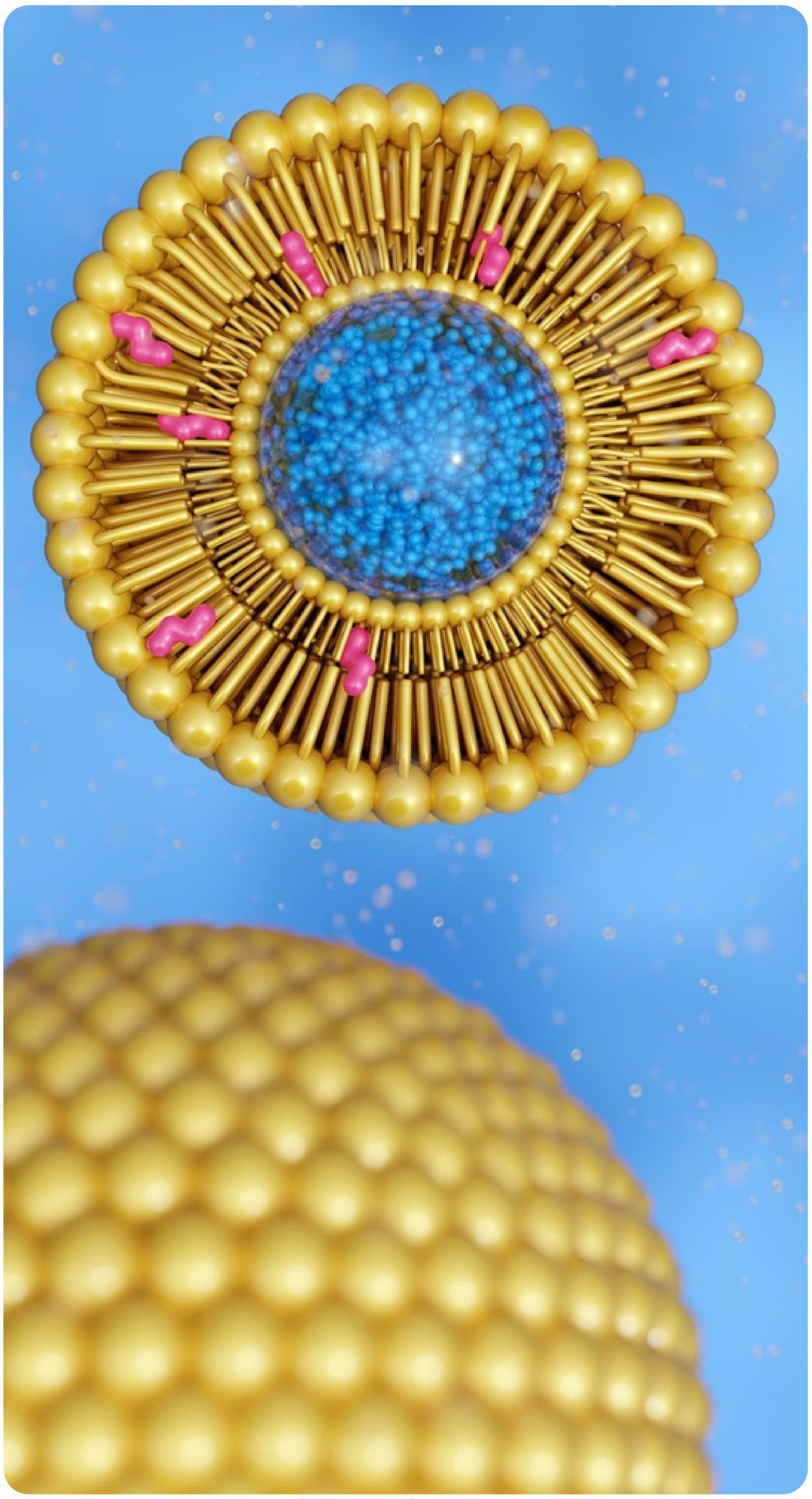
- Successful completion of the pharmacokinetic and tissue distribution study
- Regulatory-ready study documentation prepared for global submissions
- Study reports submitted to the U.S. Food and Drug Administration and European Medicines Agency
- Supported the sponsor's successful market approval process in both regions

Scientific Highlights

- Expertise in handling complex liposomal formulations
- Advanced LC-MS/MS capabilities for challenging bioanalytical studies
- End-to-end support for pharmacokinetic and tissue distribution studies
- Strong regulatory compliance aligned with global agency expectations

References

- Brüggemann RJ, Jensen GM, Lass-Flörl C. Liposomal amphotericin B-the past. Journal of Antimicrobial Chemotherapy. 2022; 77(Suppl 2): ii3–ii10.



India: +91 79677 73000
Europe: +30 210 699 7247

info@veedalifesciences.com

www.veedalifesciences.com

Excellence In Everything