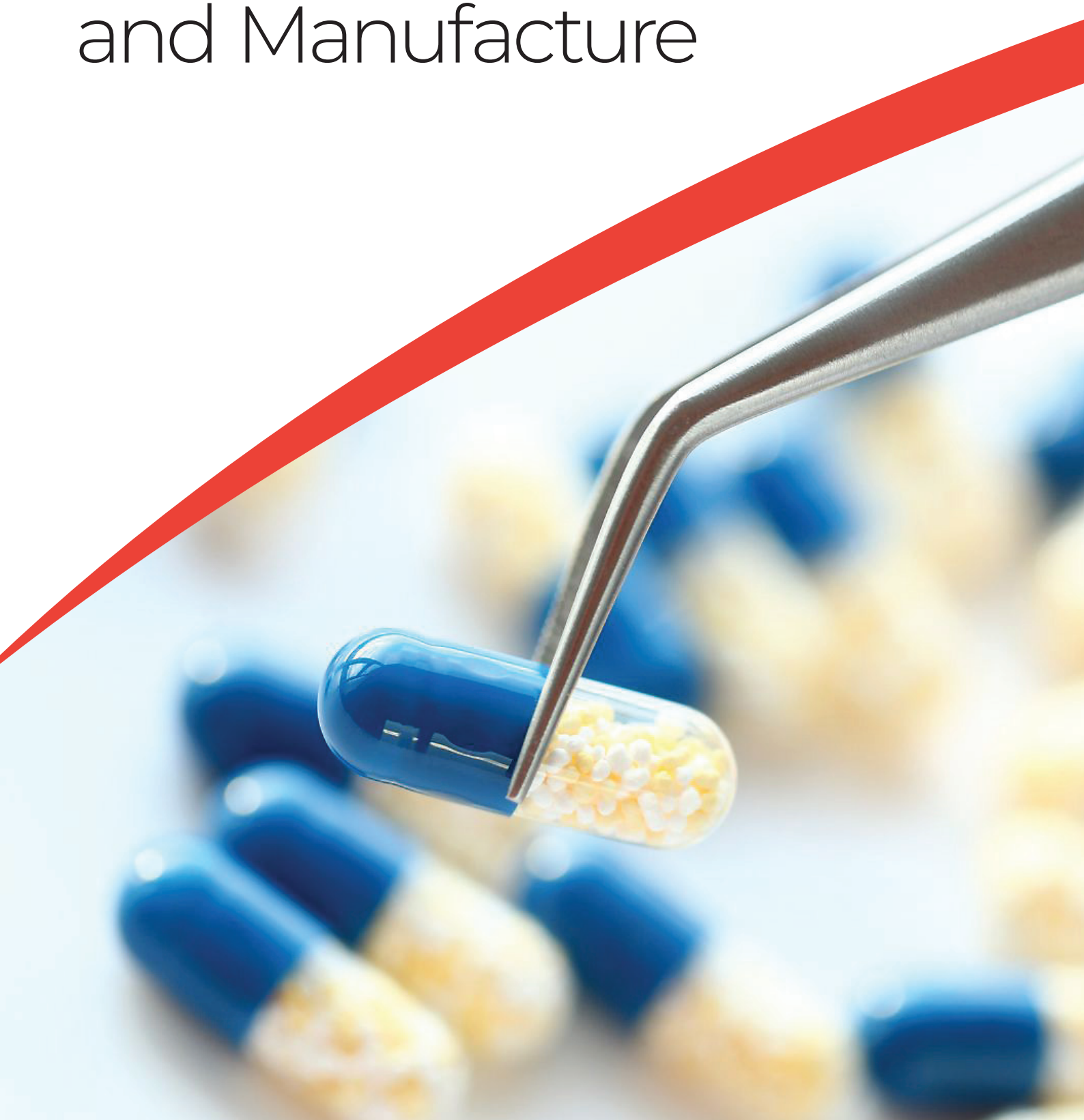
ALMAC

Partnering to Advance Human Health

Brochure

Potent Processing and Manufacture



With over 50 years' experience and a commitment to excellence, Almac specialises in the processing and manufacturing of potent compounds, ensuring the highest quality and safety standards. At Almac, we understand the unique challenges associated with handling potent compounds. Our highly skilled team is equipped to handle a diverse range of Active Pharmaceutical Ingredients (APIs) and drug products utilising state-of-the-art facilities, equipment, and technology. Following rigorous containment protocols to protect both our employees and the environment, ensuring both safety and compliance at every step.

We have a wealth of experience processing high potency APIs in drug product development, for clinical trial supply and commercial products. Almac develops and manufactures oral dosage formulations containing high potency API from our non-GMP and GMP facilities, with batch sizes ranging from mgs up to 250kg.

Before any processing begins, Almac will assess the health and safety implications of an API. The molecule's OEL (occupational exposure limit) is used to assign it to one of five bands. The assigned band is then used as part of a detailed process risk assessment.

Where appropriate, Almac can use a range of proven engineering controls to minimise exposure potential during transfer and processing.

Examples of engineering controls include:

- Ventilated enclosures
- Isolators
- Enclosed gravity feed systems
- Split butterfly valve systems
- Enclosed vacuum transfer systems
- EZ-dock valve systems

Custom built infrastructure

Almac routinely processes compounds with OELs as low as 0.05g/m3/8 hours and we are dedicated to providing safe, high potency processing for our clients.

Almac also performs a separate, health-based risk assessment to minimize potential product cross contamination. We use either the PDE (permitted daily exposure) or ADE (acceptable daily exposure) to set cleaning validation and cross contamination limits. Cleaning limits consider a number of factors including dose of the drug in the next batch, total product contact surface of the equipment and minimum batch size.

We have the capability to process potent compounds using a wide variety of processing techniques, which include:

- Dispensing
- Blending
- Dry granulation
- Wet granulation / fluid bed drying
- Compression
- Encapsulation
- Tablet coating

We understand that every project is unique, and we take pride in providing tailored solutions to meet your specific project needs. Our experienced team works closely with you to understand your requirements, offering flexible options and customised processes. From formulation development, to scale-up and, commercial manufacturing, Almac is your trusted partner throughout the lifecycle of your drug product.

Why choose Almac?

- Highly experienced, dedicated, and expert teams
- Industry leading project management
- Flexibility to meet your growing needs
- Reputation for quality
- Results driven
- Collaborative partnership
- One global Quality Management System
- Continual investment in our people, facilities, capabilities, and technology

Scan the QR Code to learn more about our commercial solutions.

almacgroup.com

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