

Paediatric Drug Development and Manufacture





At Almac we understand the unique challenges faced in developing and manufacturing medications specifically tailored for paediatric patients. We offer comprehensive solutions which ensure the safety, efficacy, and appropriate dosing of medications for children. Our experienced team will partner with you to meet the highest level of regulatory standards for your paediatric drug product throughout its lifecycle.

Customised Formulation Development

We recognise that paediatric patients span a wide age range, from newborn to adolescents and all have unique needs and requirements. Our formulation development scientists specialise in creating age appropriate and palatable drug formulations. Considering factors such as taste, texture, dosage forms and, ease of administration, we develop formulations that are both effective and well-tolerated by paediatric patients.

Regulatory Expertise

The development of paediatric medications involves navigating various complex regulatory requirements. Regulatory agencies have specific guidelines for paediatric drug development to ensure patient safety and efficacy. This regulation aims to ensure that medications for use in children are of high quality, ethically researched and authorised appropriately,

and improving the availability of information on the use of medicines for children. We have a wealth of experience in these requirements and can support you to ensure your paediatric product will meet the highest standard of quality and safety for your patients.

Dosage Accuracy

Accurate dosing is critical for paediatric medications, as under-dosing can result in therapeutic failure, and overdosing can lead to adverse and sometimes critical effects. However, dosing accuracy is challenging due to variations in body weight, age, and developmental stages in children. We ensure that formulations are checked and weighed throughout the manufacture process to ensure accuracy in dosage forms. Also, delivering an assortment of oral dose medications in weighed solutions such as granules, mini-tablets and tablets in stick packs and sachets, to enable correct dosage amounts.

State-of-the-Art Manufacturing Facilities

Our manufacturing facilities are equipped with cutting-edge technology to produce the highest quality medications. Our manufacturing capabilities include:

Dosage Accuracy

- Dispensing
- Blending
- Dry granulation/roller compaction
- Wet granulation/fluid bed processing
- Automated (mini) tablet compression
- Mini tablet coating
- Mini tablet encapsulation

Bulk Unit Forms

- Mini tablets
- Powders/granules
- Liquids
- Orodispersible

Dosing

- Stick-packing
- Sachet filling
- Powder in bottle filling
- Liquid filling

Complex kit assembly solutions are also available for paediatric dosage forms.

Almac's experienced Pharmaceutical Development team successfully delivered multiple Paediatric formulations through development, commercial manufacture, packaging, and ongoing lifecycle supply. Our expertise extends to commercial manufacturing of these, often small scale/low volume, products coupled to our ability to offer innovative packaging solutions particularly suited for Paediatric medicines. Providing these services from a single source assures you that the formulation and processing knowledge gained throughout development phase is effectively transferred to ongoing commercial supply.



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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