ab initio pharma

R&D & GMP NASAL PRODUCTS

Nasal Product Development and GMP Manufacturing Services

Empowering Your Nasal Product Innovations

Ab Initio Pharma

Your Partner in Nasal Product Excellence

Ab Initio Pharma Pty Ltd is at the forefront of nasal product development and manufacturing. With over two decades of specialised experience in aerosol science, our expert team at Ab Initio offers comprehensive services tailored to the development and production of advanced nasal delivery systems. Our state-of-the-art facilities are strategically located in Camperdown, Sydney, at our new purpose-built GMP facility on the Royal Prince Alfred Hospital grounds with our R&D Facilities located in Macquarie Park Innovation District: the PharmaHub of Australia.

Our Capabilities

At Ab Initio Pharma, our formulation expertise encompasses a diverse range of nasal delivery systems including solutions, suspensions, and powder-based devices. We cater to a broad spectrum of pharmaceutical needs, from generic formulations to small molecule New Chemical Entities (NCEs) and complex biologicals (including RNA, proteins, and peptides). Our approach is designed to ensure precision, efficacy, and safety across all stages of product development. With our state of the art cGMP manufacturing facility we produce both liquid and powder nasal aerosols for clinical trials.

Nasal Product Development

Ab Initio has extensive experience in formulation, testing and manufacturing of conventional nasal spray systems. Our dedicated Nasal R&D Department can formulate an API into a suitable platform for the intended indication. We offer full CMC services and support IND activities to customers worldwide.

Ab Initio has developed both locally acting nasal products as well as complex targeting formulations including vaccine delivery and molecules for systemic and brain targeting.

Solution & Suspension Nasal Devices

Our team excels in the stabilisation and homogenisation of suspension formulations. By finely tuning the suspension characteristics, we ensure consistent delivery and dosage of active ingredients, including poorly soluble molecules and advanced biologics that require suspension mediums for stability.

Powder Nasal Devices

Leveraging advanced particle engineering technologies, we develop dry powder formulations suitable for nasal administration. This includes the use of carrier systems for enhanced delivery of macromolecules such as proteins, peptides, and RNA-based therapies. Our formulations are designed to achieve optimal particle size for deep nasal cavity penetration while maintaining the integrity and bioactivity of the therapeutic agents.

Customisation for Generics & Innovator Drugs

We provide comprehensive formulation services for both generic nasal therapies and breakthrough NCEs. Our capabilities include evaluation of innovator products, product matching and improvement of existing formulations, as well as design and development of novel delivery systems for NCEs.

Pre-Clinical Testing Services & Bioequivalence

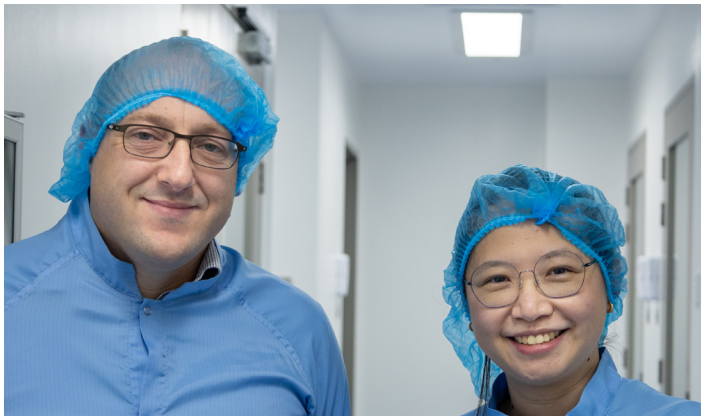
Toxicity and Transport Studies: Utilizing specific nasal cell types, we conduct in-depth pre-clinical toxicity and cell response studies to pre-emptively address potential clinical issues. Our transport studies assess the deposition and pharmacokinetics of nasal formulations, ensuring they meet therapeutic targets effectively. These in-house techniques allow us to compare new and existing formulations as well as evaluate the impact of excipient modification (i.e. the removal of a preservative or the addition of penetration enhancers).

Nasal Product Testing Facility

Our R&D and GMP labs are equipped with pharmacopoeia testing apparatuses as well as advanced techniques including in-line laser diffraction, nano and micro-particle analysis, thermogravametic analysis, vapour sorption, rheology and electron microscopy. Our facility can perform detailed characterization of nasal spray products; data vital for regulatory submissions.

GMP Manufacturing

Ab Initio's GMP licence covers a wide range of therapeutic classes from potent NCEs to scheduled drugs. Our manufacturing facility produce both liquid and powder formulations including precision liquid fill and high sheer nasal solutions and suspensions, or nasal powders produced through particle engineering and processing (freeze drying, spray drying, micronisation etc.). We also have in house capability to fill pressurised systems including HFA and low GWP propellants.



Ab Initio has in house QC, an can release for supply as well as conduct formal stability programs for shelf life assignment and CMC packages. Our validated blinding protocols, packaging facilities and QMS ensure your product is in safe hands and reaches the trial site as a high quality reliable finished dosage form.

Conclusion

Transform your nasal product concept into a market-ready solution with Ab Initio Pharma. Contact us to learn how we can support your product development journey.

ABOUT AB INITIO PHARMA

Ab Initio Pharma, is a licensed GMP manufacturer (TGA Licence: MI-2012-LI-02662-3, APVMA Licence: 3016), specialising in formulating and manufacturing pharmaceutical goods. Ab Initio can take molecules from initial discovery to clinical trial products and commercialisation.

CONTACT

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