

Alcohol-free and on-the-go oral care — development and manufacturing.

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What we do and do not do

ORALABX develops and manufactures oral care products for brand owners, innovation teams and external partnership teams. We are engaged either before a specification is fixed, to establish what is feasible, or after it is fixed, to take it into validated production. This document sets out what we do, what we do not do, and what can be verified at which stage.

IN SCOPE	OUT OF SCOPE
Mouthwash and oral rinses	US OTC monograph drug products — these follow a different regulatory pathway and are evaluated separately
Toothpaste and gels	
Breath sprays and oral mists	Ingredient and active discovery, and licensing of our own formulations
Unit-dose sachets, stick packs and travel formats	
Alcohol-free and low-alcohol systems	Devices, electronics and diagnostics
Mineral, zinc and xylitol systems	Bulk liquid and semi-finished supply — we supply finished, packaged, export-ready goods only
Flavour and sensory reconstruction	
Cosmetic-pathway documentation support	Own-brand products sold into our customers' markets

Technical platforms

These are the areas where we hold working experience rather than general capability.

Alcohol-free system design
Removing ethanol changes solubilisation, preservation, flavour delivery and perceived efficacy at the same time. Rebuilding all four together is the actual development problem.

Freshness duration and odour control
Formulation and dosing work aimed at how long the effect is perceived, not only at the strength of the initial impression.

Mineral and non-fluoride systems
Hydroxyapatite, zinc and xylitol systems, including stability and sensory behaviour in the finished pack rather than in the laboratory alone.

On-the-go formats and dosing
Spray dosing and atomiser selection, single-use sachet and stick-pack filling, and travel pack sizes designed for use away from a sink.

Sensory and flavour reconstruction
Flavour systems for high-humectant and alcohol-free bases, where a flavour that performs in a standard base will not transfer directly.

How a project runs

01 Concept and technical alignment
We confirm what is technically and commercially possible before development starts, including regulatory pathway, format limits and packaging constraints.

02 Formulation development
Two to three directions are usually developed in parallel rather than one, so the decision is made on comparison.

03 Prototype sampling
Prototype samples for internal evaluation, followed by a revision round against structured feedback.

04 Technical evaluation and optimisation
Stability, compatibility and applicable third-party testing before any commitment to production.

05 Commercial scale-up
Documented, repeatable manufacturing under our quality management system.

100 ml prototype → 20-40 testing units → pilot production → 10,000+ units per SKU commercial manufacturing
Formulation, testing and manufacturing can be engaged separately or as a single programme.

Quality and testing

QUALITY FRAMEWORK		
Standard	Applicable operation	Verification
ISO 9001	Quality management system	Certified
ISO 14001	Environmental management system	Certified
ISO 22716	Cosmetics good manufacturing practice	Certified
GMPC	Good manufacturing practice for cosmetics	Certified
SMETA	Ethical and social compliance	Audited
FDA MoCRA	US facility registration	Registered

INTERNAL TESTING
Incoming material inspection, in-process quality control, finished-product quality control, pH, microbiological testing, packaging compatibility, leak testing, and finished-product stability over 90 to 180 days.

THIRD-PARTY TESTING	
Carried out at internationally accredited (ISO/IEC 17025) laboratories, to the following standards.	
Test	Standard
Preservative efficacy	ISO 11930, USP <51>
Microbial limits	USP <61>
Absence of specified microorganisms	USP <62>
Heavy metals	EC 1223/2009, USP <232>
Packaging migration	D0 and D28
In-vitro antibacterial	QB/T 2738, GB 15979 — S. mutans, P. gingivalis, F. nucleatum
Whitening	ADA method

Documentation availability

We publish what exists and at which stage it becomes available, rather than offering an undefined qualification pack.

Document	Stage available	Availability
Capability summary	Published	Direct download
Certification names, scope and issuing bodies	On request	Public
Standard supplier documentation list	On request	Public
Certificate numbers and copies	Supplier qualification	Named recipient
Manufacturer identity and facility qualification documents	Under NDA, if the project proceeds	Confidential
Project-specific technical and test documentation	Under NDA, project-specific	Confidential
Neutral laboratory evaluation samples	After technical discussion under NDA	Confidential

Audit arrangements are supported and agreed with the manufacturing site at the appropriate stage.

IP, confidentiality and anonymity

Ownership
Formulation developed for a client to an agreed brief belongs to that client. Our existing technical know-how, development platforms and manufacturing experience remain our background know-how. Our objective is to make ownership boundaries explicit before development starts, rather than relying on assumptions afterwards.

Confidentiality
We do not publish client names, brands or project details, including for completed work. Any case material we share is anonymised.

Anonymous processes
We are used to working with intermediaries who cannot disclose the end client during screening, and we do not require disclosure in order to respond to a technical brief.

Export
Approximately 85% of output is exported; North America is the largest destination, followed by Europe and the UK, the Middle East and Australia

Supply form
Finished, packaged, export-ready goods only

Working with us
If you are screening partners for a defined need, a short written brief is enough to get a substantive answer. You do not need to identify your client, and no NDA is required for an initial discussion. We reply in writing within three business days, including when the answer is that the need falls outside our scope.

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