

SIKALIAS

PHARMACEUTICAL LABORATORIES

Corporate Profile — Development, Scale-Up & Contract Manufacturing

Two GMP sites in Peristeri | From client brief to industrial manufacturing



www.sikalias.com | info@sikalias.com

1. Executive summary

Sikalias Pharmaceutical Laboratories operates as a development-to-manufacturing partner for pharmaceutical, nutraceutical, medical device, FSMP and cosmetic companies.

The company combines formulation development, analytical development, stability studies, pilot work, process transfer and industrial-scale manufacturing in one documented workflow.

- 20+ partner companies and 120+ entrusted products
- Two complementary sites in Peristeri
- Flexible model for smaller development-driven batches and larger commercial campaigns
- Client-first operating model, with own brands kept limited to avoid competing with clients

2. Development-to-manufacturing workflow

A typical project starts from the client brief and moves through controlled development and manufacturing stages.

Client brief → Formulation development → Analytical development → Stability studies → Pilot batches → Process transfer → Industrial scale-up → Technical package handover → Manufacturing

Regulatory ownership remains with the client-appointed regulatory office and/or MAH structure. Sikalias supports the technical package, scale-up, manufacturing readiness and QA-led compliance interface.

3. Two-site operating model

SITE 0 — 7 Kyklaminon Str., Peristeri 12137 R&D, analytical work, pilot support, QC and GMP operations for selected non-sterile liquid / semi-solid formats. Batch certification, packaging support and chemical / physical QC.	SITE 1 — 3-5 Stylianou Gonata Str., Peristeri Industrial Zone 12133 Larger GMP lines and broader dosage-form scope. Solid dose, powders/sachets, sprays, drops, liquids and flexibility for larger commercial campaigns.
---	--

Together, the two sites create operational flexibility, better transfer from development to manufacturing and stronger continuity of supply.

4. Authorized manufacturing scope

Depending on product category and project requirements, the manufacturing platform supports:

- External-use liquids: dermal solutions, pharmaceutical soaps, emulsions
- Internal-use liquids: oral sprays, oral solutions, syrups, suspensions, oral drops
- Nasal solutions and nasal sprays
- Otic drops
- Semi-solids: creams, ointments, gels
- Tablets: plain, effervescent, lozenges, coated
- Hard capsules
- Powders and effervescent powders in sachets

5. Technical platform advantage

- Low-humidity operations with the ability to go below 10% RH for moisture-sensitive or hygroscopic formulations
- Powder filling into bottles for products reconstituted into suspensions
- Solid-dose packaging in PVC/Alu blisters, Alu/Alu strips or bottles
- Automated lines for nasal solutions / sprays and oral sprays
- Automated packaging line for otic drops
- Automated packaging line for oral solutions, syrups and suspensions
- Nitrogen capability for formulations containing oxidation-sensitive ingredients



6. Quality and compliance framework

Sikalias follows a QA-led compliance model. The regulatory-compliance interface is integrated within QA and focuses on the technical documentation and compliance requirements needed for development, scale-up and industrial manufacturing.

- GMP operations and National Appendix for the sites
- ISO 9001:2015, ISO 13485:2016 and EN ISO 22716:2007
- Technical documentation generated through development
- Manufacturing and scale-up documentation aligned with GMP, ISO and product-specific requirements
- Coordination with the client-appointed RA / MAH structure where required

7. Client value proposition

- Development depth: from brief to technical package
- Manufacturing flexibility: smaller and larger GMP batches
- Continuity of supply: two-site production security
- Technical edge: low humidity, nitrogen capability and automated lines
- Client-first manufacturing approach

8. Contact

Sikalías Pharmaceutical Laboratories SA

7 Kyklaminon Str., 12137 Peristeri, Greece

3-5 Stylianou Gonata Str., 12133 Industrial Zone of Peristeri

Tel. +30 210 5720900

info@sikalias.com

www.sikalias.com

Source framework

EOF GMP package / production authorization for Site 0 and Site 1; ISO 9001:2015, ISO 13485:2016 and EN ISO 22716:2007 certificates. Internal technical details incorporated based on company-provided operational information.