

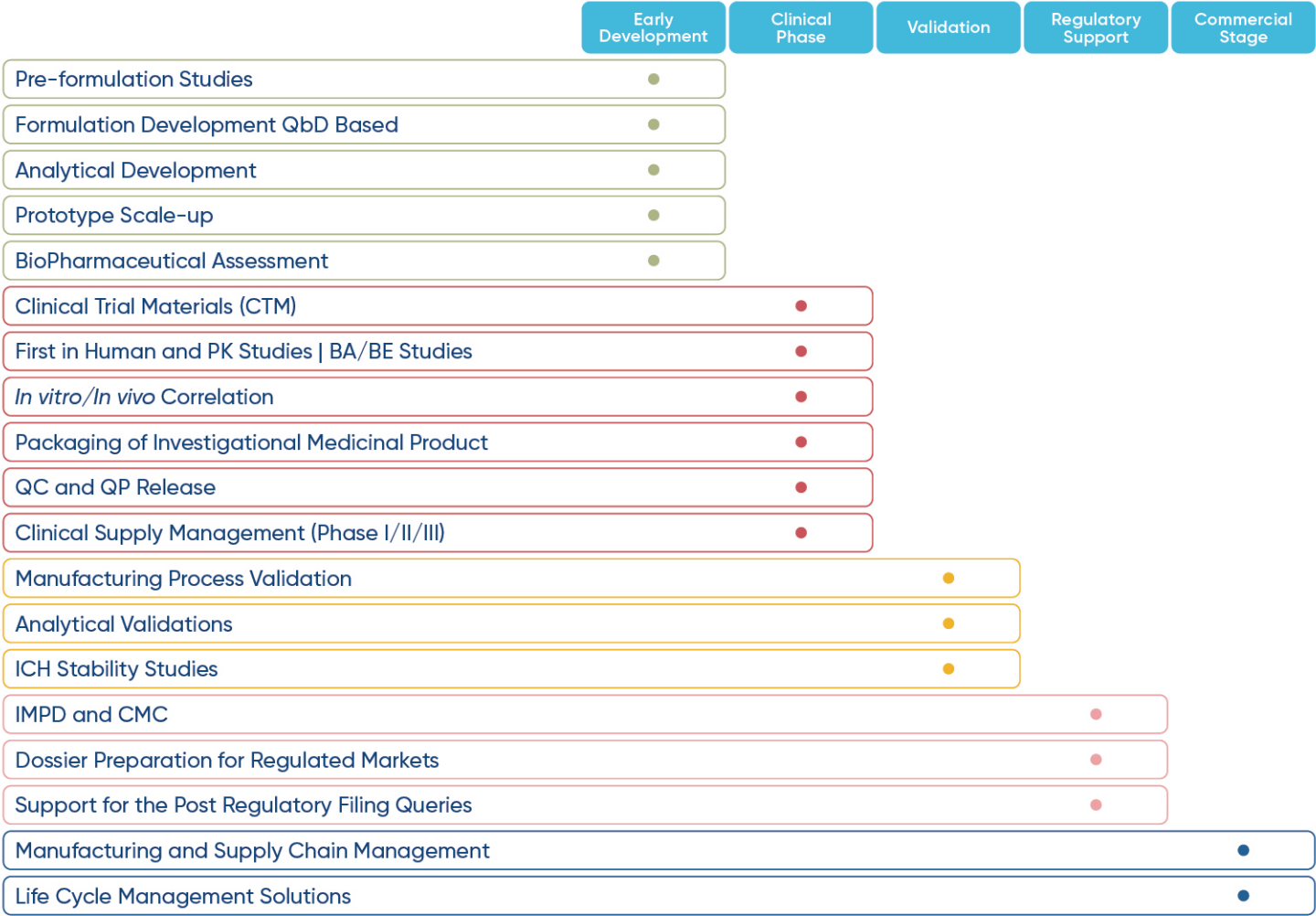
A black and white photograph of a long, empty hallway with glass doors on the left and solid doors on the right. Two individuals wearing full white protective suits, including hoods and masks, are walking towards the camera from the end of the hallway. The lighting is bright and even.

your
partner
that
cares

**DEVELOPMENT &
MANUFACTURING
CAPABILITIES**

 **bluepharma**

Unlocking the full potential of your products with our integrated technical solutions and global supply chain from Europe.



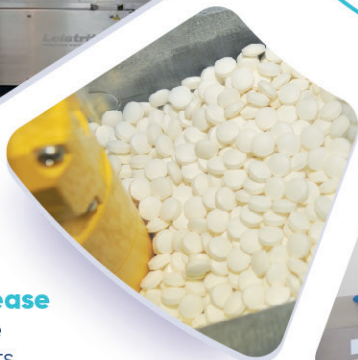
We offer **tailored solutions** and a **collaborative partnership** that truly values your vision.

Unlocking the full potential of your molecules with our comprehensive CRDMO-driven technical solutions.

Technologies & Platforms

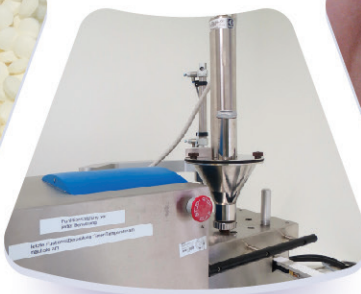
Oral Solids

- High Potent Molecules
- Controlled Substances



Modified Release

- Matrix Release
- Coating Agents
- Pellets and Beads
- Dual Release Layers



Hot Melt Extrusion

- Conventional and HPAPI Molecules
- Taste masking solutions
- Lab and Commercial Scale

Complex Sterile

- Liposomal Formulations
- Lipid-based Nanoparticles
- Polymer-based Nanoparticles
- Solid Sterile Formulations



Oral Mucosal Delivery

- Buccal Sprays **BlueEase™**
- Oral Dispersible Tablets
- Sublingual/Buccal Tablets
- Oral Thin Films **BlueOS®**



Comprehensive Solutions backed by
End-to-End Analytical Expertise and
Advanced Techniques.

Bluepharma offers
an integrated
approach, providing
support on all steps
of the product
development, **from
R&D to market.**

Integrated CRDMO

ASSETS AND INFRASTRUCTURE



3 R&D CENTERS

Dedicated to Innovation with expertise in Oral and Injectable Forms.



2 COMMERCIAL MANUFACTURING

Unlock Success with Bluepharma: Global Reach and a Proven Track Record of Success.



1 GMP PILOT SCALE AREA

- Tailored small GMP batches including highly potent products reducing the API needs.
- Ideal for clinical manufacturing from Phase I to III studies.



mRNA & ADVANCED THERAPIES HUB

Dedicated to nucleic acids and advanced therapies comprising:

- Lab-scale center for knowledge and technology translation.
- Development, process engineering and scale-up center.
- Highly specialized GMP Center for manufacturing clinical and commercial batches of complex injectables (ready in 2025).

Certified by the main entities



Bluepharma

INDUSTRIAL UNIT I – SÃO MARTINHO BISPO (SMB)

Bluepharma manufacturing sites are located in Europe (Portugal) for the production of medicines worldwide.

Bluepharma is prepared to produce **3 billion units of oral solid pharmaceutical forms** (tablets and capsules) per year, making use of up-to-date technology and the latest offer in equipment.

Its market competitiveness is also ensured by the use of management techniques based on Lean 6-Sigma methodology.

over
15%
R&D Investment

over
40
International Territories

over
120
International Clients

over
750
Employees in
the Company

over
60
Active Substances
(used in manufacturing)



Fully integrated
development
and commercial
manufacturing.



Opioids
Controlle
substances



State of the art
containment
technology.



Up to **330k**
tabs/h

Up to **600**
blisters/min

Up to **150k**
caps/h

Up to **50**
bottle/min

Bluepharma

INDUSTRIAL UNIT II – EIRAS

Bluepharma opened a **state-of-the-art industrial unit specialized in the production of oral solid high potent drugs**, namely in the oncology area. One of the largest in Europe for the production of medicines with these specifications.

The new industrial unit, equipped with the latest technology, has an **annual production capacity of 300 million units**.



On Time
in Full



Reduced
Lead Time



Right First
Time



Lean Six
Sigma



Up to **180k**
tabs/h



Up to **200**
blisters/min



Up to **45k**
caps/h



Up to **100**
bottle/min



scan me
State-of-the-art
industrial unit video



Fully integrated
development
and commercial
manufacturing.



Opioids
Controlle
substances



State of the art
containment
technology.
OEL up to $< 0.03 \mu\text{g}/\text{m}^3$



Development Capabilities

ORAL SOLID DOSAGE FORMS AND HIGH POTENCY PRODUCTS

Process Equipment Capacity	Blending	2 UNIVERSAL DRIVE UNITS/BLENDERS	< 12 L (2 units), < 10 L, < 3 L, < 1 L, < 200 mL, 250mL and 500 mL
		OST BASIC OVERHEAD STIRRERS	≤ 20 L
		ULTRA TURRAX DI 25 BASIC DISPERSER	≤ 2 L
		IKA EUROSTAR 20	≤ 15 L
	Wet Granulation	MINI-GLATT 3 FLUID BED GRANULATOR/DRYER	25 g to 375 g
		SOLIDLAB 1 FLUID BED GRANULATOR/DRYER	100 g to 800 g
		GLATT TMG V6 TABLE HIGH-SHEAR GRANULATOR/BLENDER	2 bowls (< 0.5 L, < 2 L and > 6 L (min: 20%))
		SYNTEGON MYCROMIX HIGH-SHEAR GRANULATOR/BLENDER	2 bowls (< 2,5 L and < 5 L)
	Tableting	RONCHI FA/8 ROTARY TABLET PRESS	8 stations "D"
		STYL'ONE EVO	Compression/Compaction Simulator - B+D tools
	Coating	GLATT GMPC MINI PERFORATED COATING PAN	0.8 L and 2 L (min: 200 g)
		SYNTEGON SOLIDLAB 1 PERFORATED COATING PAN	1 L and 2 L (250 g to 1000 g)
	Sieving	ERWEKA OSCILLATING SIEVE	Different sieve sizes available
		COSMEC ROTATING SIEVE	Different sieve sizes available
		SHAKTI CONICAL MILL	Different sieve sizes available
	Micronization	DEC MC2 JETMILL (down to 3µm)	1.5 g up to 200 g/hr
	Capsule Filling	INCAP CAPSULE FILLING MACHINE (filling of powder, microtablets and tablets into capsules)	Min. 100 g (Dosing Disk & Dosators)
	Hot Melt Extrusion	MINILAB EXTRUDER	Up to 100 g/hr
	Other	FDF TWO-STATION LIQUID DOSING AND FILLING UNIT	≤ 1.200 fills/h
		IKA M20 DRY MILL	< 250 mL

SCALE-UP OF ORAL SOLID DOSAGE FORMS AND HIGH POTENCY PRODUCTS

Process Equipment Capacity	Blending	LB BOHLE PM400 BIN BLENDER	Up to 400 L
	Wet Granulation	COS.MEC MGR 40 HIGH SHEAR GRANULATION	Up to 15 kg
		BOSCH SOLIDLAB2 FLUID BED DRYER/GRANULATOR	Up to 12 kg
	Sieving	FREWITT OW3 OSCILATING SIEVE	Different sive sizes available
	Tableting (features available: multitip punches, microtablets, multilayer)	KILIAN KTP 180 X (with EU-B (19) or EU-D (13) punch station)	Up to 79800 tabs/h (EU-D)
	Coating	BOSCH SOLIDLAB2 DC (batch size up to 24Liter)	Up to 12 Kg
	Capsule Filling	ZANASI 40E (features available: powder filling, capsule sorting (100%), pellets, microdosage)	Up to 40.000 caps./h
	Hot Melt Extrusion	LEISTRITZ ZSE 18HPE HOT-MELT EXTRUDER	From 200 g/h to 40 kg/h
	Packaging	CP2 (Scale-up LAB)	Max. 120 blisters/min

Manufacturing Capabilities

INDUSTRIAL UNIT I • SÃO MARTINHO DO BISPO

Process Equipment Capacity	Blending (bin blending with a range of IBC for pilot and commercial manufacturing up to 2000 L). Available IBC: 50 L, 80 L, 100 L, 400 L, 800 L, 1200 L, 1800 L, 2000 L.	BOHLE PM 1000	Up to 1.200 L
		BOHLE PM 2000	Up to 2.000 L
	Dry Granulation	ALEXANDERWERK WP 50 compactor	Up to 40 kg/h
		ALEXANDERWERK WP 120 PHARMA (with R&D/Industrial purposes/flexibility)	From 5 g to 40 kg/h
		BOHLE BRC 25	Up to 100 kg/h
	Wet Granulation	LODIGE MGT 250 + ALEXANDERWERK R300 + GLATT WSG 60	Up to 250 L
		GLATT VG6000 + WSCOMBO 450 (high shear granulation, fluid bed granulation and Würster process)	Up to 600 L
		SYNTEGON Granulean 600L (high shear granulation, fluid bed granulation/drying)	Up to 600 L
	Tableting (features available: multitip punches, microtablets, multilayer)	1 KILIAN TX (with 40 type EU-B punch stations)	Up to 250.000 tablets/h
		1 KILIAN TX (with 26 type EU-D punch stations)	Up to 250.000 tablets/h
		2 KILIAN SYNTHESIS 500 (with interchangeable turret for EU-B (45) / EU-D (30) punches)	Up to 300.000 tablets/h
		1 KORSCH XL 400 MFP (multilayer press)	Up to 330.000 tablets/h
		2 KILIAN KTP 420X (with interchangeable turret for EU-B (45) / EU-D (30) stations)	Up to 324.000 tablets/h
		1 KILIAN KTP 590x (multilayer press) <small>new / 2024</small> (with interchangeable turret for EU-B (64) / EU-D (44) stations)	Up to 460.000 tablets/h
	Coating	GLATT GC SMART 350	Max. 280 kg cores/coating step
		GLATT GCC 250L	Max. 200 kg cores/coating step
	Capsule Filling (features available: powder filling, capsule sorting (100%), microtabs, pellets, microdosage)	ZANASI PLUS 85E	Up to 85.000 caps./h
		BOSCH GKF 2500	Up to 150.000 caps./h
		SYNTEGON KKE2500 (capsule sorter on-line or off-line)	Up to 150.000 caps./h

Highly qualified and experienced R&D team

Manufacturing Capabilities

INDUSTRIAL UNIT I • SÃO MARTINHO DO BISPO

Bluepharma's current capacity is approximately 60 million packs yearly. Packaging operations are performed in accordance with all cGMP standards, using cutting edge packaging lines with the following features:

Blistering	PVC Alu	
	PVC-PVDC Alu	
	PVC-PE-PVDC Alu	
	PVC-PCTFE Alu	
	OPA Alu	
Bottle Filling	HDPE bottles semiautomatic line - counting/capping/induction sealing COUNTEC + HERMA integrated line with DOMINO serialization solution - max (45 bottles/min)	
Serialization and Aggregation	DataMatrix <ul style="list-style-type: none">• Unique Identifiers application as per FMD requirements• 2D (DM core) compliant with worldwide regulation	
	ARVATO software <ul style="list-style-type: none">• ERP integration• Solution Level 2,3,4,5	
	OCS and Domino hardware solutions	
	Tamper evidence (transparent round perforated label)	
	Case Level + Pallet level aggregation (as per FMD/DSCSA requirements)	
Labeling	Applying bollinos	
	Checking	
Mediseal packaging lines	1 x CP2 (Scale-up LAB)	Max. 120 blisters/min
	3 x CP400 + P1600	Max. 400 blisters/min
	1 x CP400 + P3000	Max. 400 blisters/min
	2 x CP600 + P5000	Max. 600 blisters/min
Sachets line	EFFYTEC HB32	Max. 300 sachets/min

STABILITY CHAMBERS - TO SUPPORT STUDIES UNDER THE FOLLOWING CONDITIONS

	Climatic Zone II	Climatic Zone IVa	Climatic Zone IVb	Accelerated Stability	Refrigerator
Temperature	25° C	30° C	30° C	40° C	5° C
Humidity	60% RH	65% RH	75% RH	75% RH	-

8
PACKAGING
LINES

Our goal
is to provide
a reliable
service.

Manufacturing Capabilities

INDUSTRIAL UNIT II • EIRAS

Process Equipment Capacity	Blending and transfer	<ul style="list-style-type: none">• Closed bin-blending system and bin-to-bin transfer system.	BLENDING I	30 – 467 L (12 – 187 kg, d= 0,4)
			BLENDING II (reserve)	Tbd according to business needs
	Wet Granulation (WG)	<ul style="list-style-type: none">• Integrated high shear mixer and fluid bed dryer in a completely closed design.• Fluid-bed granulation.• Possibility to perform coating of pellets.• ATEX & WIP execution.	WG I	300 L capacity (30 kg to 120 kg or 12 kg to 96 kg)
			WG II	Tbd according to business needs
	Roller Compaction	<ul style="list-style-type: none">• Dust-tight execution.• WIP execution.	ROLLER COMPACTION I	Up to 100 kg/h
	Tableting	<ul style="list-style-type: none">• Interchangeable turret (D/B/BB tooling).• WIP execution.	TABLETING I	Up to 180.000 tabs/h (type B)
	Capsule Filling	<ul style="list-style-type: none">• Powder and pellets filling.• Micro-dosing capability (ready to).• Upgradable for micro-tabs and caps in caps and liquids.• WIP execution.	CAPSULE FILLING I	Up to 44.000 caps/h
	Reserve	-	TABLETING OR CAPSULE FILLING	Tbd according to business needs
	Film coating	<ul style="list-style-type: none">• Perforated Pan Coater.• ATEX & WIP execution.	COATING I	175 L capacity (14 kg – 140 kg, d=0,8)
			COATING II (reserve)	Tbd according to business needs
	Hot Melt Extrusion	-	LEISTRITZ ZSE 18HPE HOT-MELT EXTRUDER	From 200 g/h to 5 kg/h

Packaging

INDUSTRIAL UNIT II • EIRAS

Blister Packaging	<ul style="list-style-type: none">• Dust-tight design.• WET execution in primary packaging.	BLISTERING I	Up to 200 blister/min.
Bottle Packaging		BOTTLING I	Up to 100 bottles/min.

Dedicated manufacturing site to handle high potent APIs.



Development Capabilities

ORAL MUCOSAL DELIVERY PLATFORMS

Bluepharma own a comprehensive know how as well as patents for buccal formulations, namely **oral sprays (BluEase™)** and **Oral thin Films (BlueOS®)** and dispose of a qualified team of scientist that are working on these technologies.

The advantages are unequivocal in what regards to convenience of use and can be adaptable to a fast onset of action.

These innovative drug delivery platforms could be explored with new molecules, in order to develop products for unmet medical needs, such as Alzheimer's, Parkinson's or ALS.

Potential Applications

- Multiple Sclerosis
- Epilepsy
- Parkinson's Disease
- Opioid Overdose
- Alcohol Use Disorder



Oral Thin Films BlueOS®	Blending	IKA MAGICPLANT	800 mL up to 2 L
	Solvent Casting	ERISHEN COATMASTER	280 cm² (between 50 to 120 units per sheet - up to 360 unit/hr)
	Film Cutting	MANUAL PRESS	1 to 4 films/movement
Buccal Sprays BluEase™	Blending	IKA MAGICPLANT	800 mL up to 2 L
		REACTOR	Up to 25 L
	Filling	ERWEKA FILLING SYSTEM	0.5 mL up to 25 mL/dosing
	Packaging/Closure	MANUAL CAPPER	Snap-on

Development Capabilities

COMPLEX INJECTABLES

At Bluepharma, **we are your trusted partner for the development and manufacturing of complex injectable drugs.**

Our team of formulation scientists and engineers leverages cutting-edge technologies to overcome the challenges of these innovative therapies.

We offer an integrated development platform, providing seamless support throughout your project journey.



Complex Steriles	Blending - Liquid Mixture/ Dissolution/Emulsion	IKA MAGICPLANT	800 mL up to 2 L
		REACTRON RT 2 & POLYTRON	< 2000 mL
		REACTRON RT 15 & POLYTRON	< 15 L
		IKA MIXER	< 25 L
		DOUBLE JACKET REACTORS	2 L, 5 L and 25 L
		VESSELS	0.250 L, 0.5 L, 1 L, 2 L and 5L
		POLYTRON PT2500	Up to 2 L
	Size reduction (extrusion, high pressure homogenization and high shear)	GENIZER EXTRUDER	10 mL to 100 mL each time / Max 80°C
		AVESTIN EMULSIFLEX TM C3	25 mL to 200 mL each time / Max 70°C
		KINEMATICA POLYTRON PT2500	Up to 2 L
	Concentration/Diafiltration Removal of Non-Encapsulated DS	SPECTRUM KROSFLO® KR2I TFF SYSTEM (with Hollow Fiber Filters)	10 mL to 10 L
		BIONET M1 BENCHTOP TFF SYSTEM	Up to 5000 mL
	Solvent Removal	HEIDOLPH ROTO-EVAPORATOR	500 mL to 3000 mL
		SPARGE RING	Up to 20 L
	Temperature control systems	BATH/CHILLER	-20°C to 150°C

GMP Clinical and Commercial Area

COMPLEX INJECTABLES

New GMP Facility overview

Total Available Space	1100 m ²
Complex Injectable Area	800 m ²
GMP Area	300 m ²

Eventual use of **High Potent API's**.

Services

- **Lipid & Polymeric Nanoparticles** platforms.
- **Analytical & Process** development and validation.
- Sterile injectable **fill and finish**.
- cGMP **clinical manufacturing**.
- **Clinical Batches**.

Process	Range	Features available
Liquid Mixture/dissolution	Up to 200L	• Homogenizers and Rotor-stator dispersers • Reactors (Double Jacket Reactors)
Emulsion	Up to 150L	Reactron & Polytron systems
Size reduction	Up to 55L each time	• Extrusion • High-pressure and High shear homogenization
Buffer Exchange	20 – 200L	• Tangential flow filtration (TFF) systems • Centrifugation
Solvent Removal	Up to 200L	• Rotor evaporators • Sparge ring • Metal porous
Sterile Filtration	Up to 200L	Pressure filtration system (for filter selection)
Fill & Capping	TBD	Vials and others under definition
Lyophilization	TBD	Under definition

Expanding
our **Integrated
solution** for
Complex Injectable
manufacturing
(ready 2025).



Bluepharma

ANALYTICAL CAPABILITIES

Bluepharma has dedicated times for:

- Development (oral solids and differentiated technologies).
- Analytical Validations.
- Analytical Tech Transfer.
- Quality Control with in House microbiology lab.
- Stability Studies.
- Project management (industrial and development).

Core Techniques

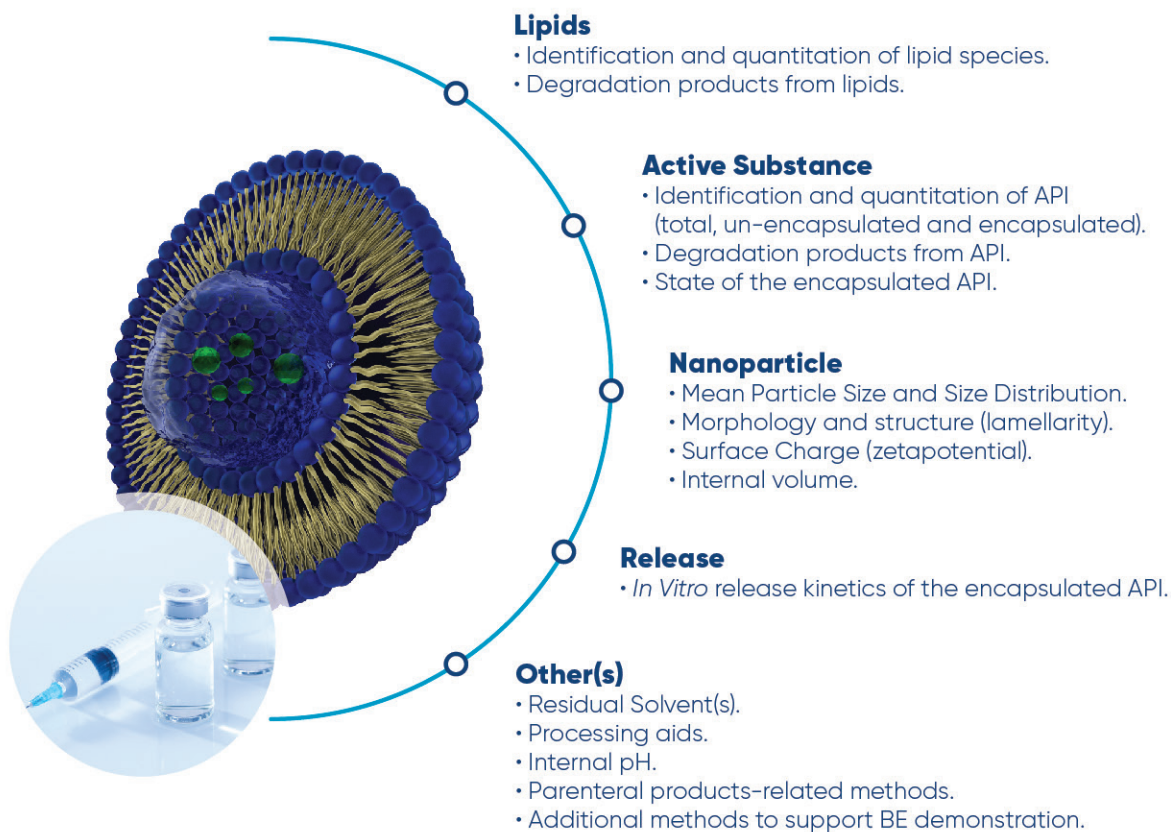
- **Chromatography**
HPLC with different detectors available (eg. PDA; RI; ELSD), GC-FID.
- **Spectroscopy**
UV/Vis, FTIR, ICP-MS.
- **Particle Size**
Laser diffraction (Malvern System).
- **Dissolution**
Apparatus I & II; In vitro release (dissolution tester with Optic UV detector).
- **Thermal Analysis**
TGA, DSC.

Advanced Techniques

- **Microscopy**
SEM, TEM (including cryo variations), Confocal Microscopy.
- **Electrophoresis**
Capillary Electrophoresis (CE), Gel Electrophoresis.
- **Nucleic Acid Analysis**
PCR and RT-PCR.
- **Chemical Imaging**
Raman Spectroscopy.
- **Biological Assays**
Cell-Based Assays (e.g., cytotoxicity).

Complementary Techniques

- Karl Fischer Titration.
- Loss on Drying.
- Solubility Studies (saking flask).
- Osmolarity.
- Zeta-potential.
- FTIR.



Bluepharma

STABILITY STUDIES

Our dedicated team ensures the stability of your drug product throughout its lifecycle, including freeze-thaw studies, transport and shipping studies, bulk holding time studies, ongoing stability studies, open-pot stability studies, forced degradation studies, and photostability studies.

STABILITY CHAMBERS

TO SUPPORT STUDIES UNDER THE FOLLOWING CONDITIONS

	Climatic Zone II	Climatic Zone IVa	Climatic Zone IVb	Accelerated Stability	Refrigerator
Temperature	25° C	30° C	30° C	40° C	5° C
Humidity	60% RH	65% RH	75% RH	75% RH	-

In-House Analytical Expertise, including complex analytical techniques.

Bluepharma

STORAGE AND WAREHOUSE CAPABILITIES

Bluepharmas has **capability to handle products** that require:

- Room temperature storage.
- Refrigerated storage (2-8°C).
- Freezer storage.
- Controlled humidity storage.
- Controlled substances storage.

Bluepharma

CERTIFICATIONS

Our proven track record of success with international regulatory inspections allows us to collaborate with leading pharmaceutical companies worldwide.

We distribute medicines across the globe, ensuring a global supply chain for **United States, Europe, Middle East, Asia Pacific, and Latin America.**



Infarmed/EMA

GMP – GOOD
MANUFACTURING
PRACTICE

Certified



Infarmed/EMA

GMP – GOOD
DISTRIBUTION
PRACTICE

Certified



FDA

U.S. FOOD
AND DRUG
ADMINISTRATION

Approved



SFDA

SAUDI FOOD
AND DRUG
AUTHORITY

Certified



MFDS

KOREA MINISTRY
OF FOOD AND
DRUG SAFETY

Certified



NHRA

NATIONAL HEALTH
REGULATORY
AUTHORITY

Certified



MoHAP

UNITED ARAB EMIRATES
MINISTRY OF HEALTH
AND PREVENTION

Certified



MSHP

MINISTRY OF HEALTH
AND PUBLIC HYGIENE
OF IVORY COAST

Certified



Ministry of Health

MINISTRY
OF HEALTH
OF OMAN

Certified



MoH

LYBIAN
MINISTRY
OF HEALTH

Certified



TMMDA

TURKISH MEDICINES
AND MEDICAL
DEVICES AGENCY

Certified



MINISTRY OF HEALTH
AND ENVIRONMENT
OF IRAQ

Certified



Let's turn your ideas into reality

Take the next step and contact us to discuss how we can collaborate on your next pharmaceutical project.



Differentiation & focus on client needs



Integrated offer
(DEVELOPMENT, CLINICAL, MANUFACTURING)



Performance and track record



Focus on time to market



Reliability and sustainability

Bluepharma's facilities are certified/approved by:

- Informed/EMA (European Union)
- US FDA (2009, 2012, 2014, 2016, 2019)
- SFDA (Kingdom of Saudi Arabia)
- MFDS (South Korea)
- MSHP (Ivory Coast)
- MOH (Libya)
- TMMDA (Turkey)

We are registered in Iraq, Taiwan, Jordan, UAE, Kurdistan, Vietnam, Bahrain and Oman.



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