



your
partner
that
cares

**DEVELOPMENT &
MANUFACTURING**

 **bluepharma**

Development Capabilities

FULLY INTEGRATED SOLUTION

	Feasibility /POC	Validation	Clinical Phase	Regulatory support
Pre-formulation studies	●			
Formulation development QbD	●			
Development of analytical methods	●			
Scale-up of prototypes	●			
Pilot BE study	●			
Validation of analytical methods		●		
Pilot batch production Validation of manufacturing process		●		
ICH stability studies		●		
Manufacturing of clinical batches			●	
Phase I studies			●	
Packaging of Human Investigational Products			●	
IMPD/CTA				●
EU-CTD // US-ANDA // other				●
CMC				●



Development Capabilities



Complex Injectables

Our commitment to advanced solutions



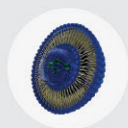
High Potency Products

Development and Manufacturing



Buccal Sprays

Innovative and versatile platforms for the delivery of drug substances



Lipid Nanoparticles (LNP)

New approach to Complex Steriles



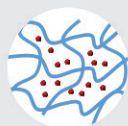
Hot Melt Extrusion

Overcoming formulation barriers



Oral Thin Films

Innovative and versatile platforms for the delivery of drug substances



Polymer-based microparticles

New approach to LAI technology



Multilayer Technology

Get more out of a single tablet



OneDose®

Unitary Dose Packaging (sachets)

Development Capabilities

DIFFERENTIATED TECHNOLOGIES

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
	Concentration/Diafiltration Removal of Non-Encapsulated DS	KINEMATICA POLYTRON PT2500	Up to 2 L
		SPECTRUM KROSFLO® KR2I TFF SYSTEM (with Hollow Fiber Filters)	10 mL to 10 L
		BIONET M1 BENCHTOP TFF SYSTEM	Up to 5000 mL
Oral Thin Films BlueOS®	Solvent Removal	HEIDOLPH ROTO-EVAPORATOR	500 mL to 3000 mL
		SPARGE RING	Up to 5000 mL
	Temperature control systems	BATH/CHILLER	-20°C to 150°C
	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



Highly qualified and
experienced R&D team

Development Capabilities

ORAL SOLID DOSAGE FORMS AND HIGH POTENCY PRODUCTS

Process Equipment Capacity	Blending	2 ERWEKA BLENDER	< 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
	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 VG600 + 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
		GLATT GC SMART 350	Max. 280 kg cores/coating step
	Coating	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

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BILLIONS
UNITS
/YEAR



On Time
in Full



Reduced
Lead Time



Right First
Time



Lean Six
Sigma

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

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PACKAGING
LINES

Our goal
is to provide
a reliable
service.

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	-

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 40 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 100 blister/min.
Bottle Packaging		BOTTLING I	Up to 100 bottles/min.

Dedicated manufacturing site to handle **high potent APIs**.



Why Bluepharma?



Flexible Business Models



International Regulatory Expertise



Global Quality Certifications



Extensive and Differentiated Portfolio

Bluepharma's facilities are **EU-GMP** certified and approved by:

- US FDA (2009, 2012, 2014, 2016, 2019)
- SFDA (Kingdom of Saudi Arabia)
- ANVISA (Brazil)
- MFDS (Republic of Korea)
- Minpromtorg (Russian Federation)
- MOH Libya
- TMMDA (Turkey)

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



scan me
Product Portfolio

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