Your partner that cares

bluepharma

Contract Development & Manufacturing

DEVELOPMENT CAPABILITIES

	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				●

FLEXIBILITY IN BUSINESS MODELS
Scale-up with or without tech transfer

DEVELOPMENT CAPABILITIES FOR ADVANCED TECHNOLOGIES

TO SUPPORT STUDIES UNDER THE FOLLOWING CONDITIONS

BlueCI Complex Injectables	**Blending**	IKA MAGICPLANT INLINE	Up to 2L
	Size reduction (features available extrusion, high pressure homgeneization and high shear)	LIPEX® EXTRUDER	Up to 10mL
		AVESTIN EMULSIFLEXTM C3	Up to 3L/hr
		KINEMATICA POLYTRON PT2500	Up to 2L
	Concentration/Diafiltration	SPECTRUM KR2I TFF SYSTEM	Up to 10L
BlueOS® Oral Thin Films	**Blending**	IKA MAGICPLANT INLINE	Up to 2L
	Casting	COATMASTER 510 (laboratorial scale)	Up to 360 units/hr

MANUFACTURING CAPABILITIES

Market competitiveness is also ensured by the use of management techniques based on lean methodology.
Highly committed on the permanent processes analysis and on the wasteful steps elimination, Bluepharma is currently developing several projects under the name Bluelean, aligned with the lean manufacturing best practices, strongly focused on the improvement of industrial and non-industrial processes and on the pursuit of adding value for our internal and external customers.
The cost optimization is embedded in the company's philosophy.
All operations undergo a comprehensive and strict quality control, from production to packaging.

PROCESS EQUIPMENT CAPACITY

Blending (bin blending with a range of IBC for pilot and commercial manufacturing up to 2000L) Available IBC: 80L, 100L, 400L, 800L, 1200L, 1800L	**BOHLE PM 400***	Up to 400 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
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 Wurster process)	Up to 600 L
	Cos.Mec MGR 40* + BOSCH SOLIDLAB 2*	Up to 15 kg
Tableting (features available: multip punches, microtablets, multilayer)	**2 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
	KORSCH XL 400 MFP (multilayer press)	Up to 330.000 tablets/h
Coating	**WALTHER PILOT**	max 40 kg of cores/coating step
	GLATT GC SMART 350	max 280 kg of cores/coating step
Capsule Filling (features available: powder filling, pellets, microtabs, microdosage)	**ZANASI 40E**	Up to 40.000 caps./h
	ZANASI PLUS 85E	Up to 85.000 caps./h
	BOSCH GKF 2500	Up to 150.000 caps./h
Hot Melt Extrusion	**LEISTRITZ ZSE 18HPe Hot-Melt Extruder***	from 200 g/h to 40 kg/h
Micronization	**DEC MC Jetmill 2*** (down 50µm)	Up to 200 g/h

HIGH CONTAINMENT MANUFACTURING

* Scale-up LAB

PACKAGING

Bluepharma's current capacity is approximately 40 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 - Unique Identifiers application as per FMD requirements - 2D (DM core) compliant with wordwide regulation	
	ARVATO software - ERP integration - Solution Level 2,3,4,5	
	DCS and Domino hardware solutions	
	Tamper evidence (transparent round perforated label)	
	Case Level + Pallet level aggregation (as per FMD/DSCSA requirements)	
Labeling	Applying bolinos	
	Checking	
Mediseal packaging lines	**1 x CP2***	max. 120 blisters/min
	3 x CP400 + P1600	max. 400 blisters/min
	2 x CP400 + P3000	max. 400 blisters/min
Sachets line	**Effytec HB32**	max. 300 sachets/min

* Scale-up LAB

STABILITY CHAMBERS

TO SUPPORT STUDIES UNDER THE FOLLOWING CONDITIONS

	Temperature	Humidity
Climatic Zone II	25ºC	60 %
Climatic Zone IV	30 °C	65 %
Climatic Zone IVb	30 °C	75 %
Accelerated Stability	40 °C	75 %

OUR GOAL IS TO PROVIDE A FULL SERVICE

DIFFERENTIATED CAPABILITIES

Multilayer Technology
Get more out of a single tablet

- Innovation and life-cycle optimisation
- Multiple API delivery
- Release profile modification
- Overcome formulation problems

OneDose®
Unitary Dose Packaging (sachets)

- Product differentiation
- Anti-counterfeiting solution
- Added value for Hospital use
- Suitable for RX, OTC and consumer Health

High Potency Products
Development and Manufacturing

- Turn-key solution
- State of the art containment technology
- New dedicated facility
- Broad high value product portfolio
- Expirienced team

Hot Melt Extrusion
Overcoming formulation barriers

- High Potenty APIs
- Controlled release
- Thermolabile
- Abuse deterrence
- Flexibility batch sizes
- Turn-key solution

Bluepharma's facilities are **EU-GMP certified. We are registered in Iraq, Jordan, Kurdistan, Taiwan, UAE and Vietnam, as well as inspected by MFDS (Korean FDA), ANVISA (Brazil), MOH Libya, SFDA (Saudi Arabia) and by US FDA (2009, 2012, 2014, 2016).**

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