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2023 | ROTTENDORF PHARMA EQUIPMENT LIST

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FDA



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Product Mastery @ Highest Standards

01 | PILOT PLANT



GRANULATION → Pilot Plant

TYPE	AMOUNT	MACHINE	STATUS	FILLING PERFORMANCE (kg)		
				minimum	optimum	maximum
HIGH SHEAR GRANULATOR / FLUID BED DRYER / GRANULATOR	01	Diosna P/VAC 10	GMP	0.4	-	4
	01	Diosna P/VAC 60	GMP	10	15	20
	01	Midi-Glatt (+ Wurster)	nonGMP	0.05	-	0.375
	01	GPCG 3 (+ Wurster)	GMP	1.0	-	3
	02	Aeromatik MP 3/4 (+ Wurster)	GMP	15	-	50
FREE FALL BLENDER	01	Bohle PM 400	GMP	20	-	200
	01	Bohle LM 20	GMP	0.1	-	10
ROLLER COMPACTOR	01	Gerteis Mini-Pactor	GMP	0.1 kg/h	-	10 kg/h
EXTRUDER / SPHERONIZER	01	GEA NICA E140	GMP	0.5 kg/min	-	2.0 kg/min
	01	GEA NICA S450	GMP	2.0 kg/cycle	-	6.0 kg/cycle
HOT MELT TWIN SCREW EXTRUDER	01	Leistritz ZSE 18HP	GMP	0.5 kg/h	-	5.0 kg/h
	01	ThermoFischer Pharma 11	nonGMP	0.02 kg/h	-	2,5 kg/h

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TABLETTING →
ENCAPSULATION →
COATING →

**TABLETTING → Pilot Plant**

TYPE	AMOUNT	MACHINE	STATUS	FILLING PERFORMANCE (pieces/h)		
				minimum	optimum	maximum
TABLETTING EURO B & D	01	Korsch XL200	GMP	10,000	-	180,000
	01	Korsch X3	GMP	10,000	-	180,000
	01	Fette 102 i	GMP	9,000	-	120,000

ENCAPSULATION → Pilot Plant

TYPE	AMOUNT	MACHINE	STATUS	FILLING PERFORMANCE (pieces/h)		
				minimum	optimum	maximum
CAPSULE FILLING	01	Bosch GKF 702	GMP	3,000	-	42,000

COATING → Pilot Plant

TYPE	AMOUNT	MACHINE	STATUS	FILLING PERFORMANCE (kg)		
				minimum	optimum	maximum
COATER	01	Bohle Film Coater (BFC) 5	GMP	01	-	05
	01	Bohle Film Coater (BFC) 50	GMP	08	-	50
	01	Bohle Film Coater (BFC) 200	GMP	150	-	250
TABLET PRINTING	01	R. W. Hartnett Delta-Printer	GMP	-	-	70,000/h

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02 | BULK MANUFACTURING



GRANULATION → Bulk Manufacturing & Large Scale

TYPE	AMOUNT	MACHINE	FILLING PERFORMANCE (kg)		
			minimum	optimum	maximum
HIGH SHEAR BLENDER / GRANULATOR, FLUID BED DRYER / GRANULATOR	02	Diosna P600	100	200	200-300
	01	Diosna P600-VAC	100	200	250-300
	01	GPCG 120	100	120	150 <i>(max. 180 only drying)</i>
	02	GPCG 200 PRO	200	250	300
	01	GPCG 200	200	250	300
	01	Aeromatik MP5	100	150	200
HIGH SHEAR BLENDER	01	Lödige 130	20	30	45
	01	Lödige 300	80	80	120
FREE FALL BLENDER	02	Bohle PM 1000	-	-	-
	03	Bohle PM 2000	-	-	1500
ROLLER COMPACTOR	02	Gerteis Macro-Pactor	1.0 kN/cm	-	20 kN/cm
DRYING CHAMBERS	04	-			
EXTRUDER	01	GEA Nica E220	50 kg/h	-	200 kg/h
SPHERONIZER	01	GEA Nica S700	2 kg/h	-	10 kg/h
SPHERONIZER	01	GEA Nica S700	2 kg/h	-	10 kg/h
FLUIDIZED BED COATER (WURSTER PROCESS)	01	Aeromatic MP5	100	150	200

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TABLETTING →
ENCAPSULATION →
COATING →


TABLETTING & ENCAPSULATION → Bulk Manufacturing & Large Scale

TYPE	AMOUNT	MACHINE	FILLING PERFORMANCE (kg)		
			minimum	optimum	maximum
TABLETTING EURO B & D	02	TX 26	24,000	-	160,000
	04	T300	12,000	-	300,000
	06	S250	7,800	-	270,000
	04	Fette F55 Bilayer Press	54,000	-	432,000
	07	Synthesis 500	28,000	-	324,000
	01	S250 ZSM (tablet in tablet)	10,000	-	85,000
	01	Korschl XL800 Bilayer Press	30,000	-	170,000
CAPSULE FILLING	02	Bosch GKF 1400	50 tacts x 10 capsules; 30,000 capsules /h		140 tacts x 10 capsules; 84,000 capsules /h

COATING → Bulk Manufacturing & Large Scale

TYPE	AMOUNT	MACHINE	FILLING PERFORMANCE (kg)		
			minimum	optimum	maximum
COATER	01	Driacoater 1600	180	250-300	400
	01	Driacoater 1600/1	200	300-350	450-500
	01	Driacoater 1600/1.25	300	450	550
	02	Bohle Coater BFC 400	300	400	500
	02	Bohle Coater BFC 600	450	600	750
SORTING	01	Sensum fully automated 100% visual inspection			630,000 tablets/h
SUGAR COATING PANS	10	120 l coating pans	40-45	60	70 kg cores (max. 150 kg final product)
	09	250 l coating pans	80	120	160 kg cores (300 - 320 kg final product)

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03 | PACKAGING



PACKAGING		
TYPE	AMOUNT	MACHINE
BLISTER LINES (FULLY AUTOMATED)	07	Uhlmann BEC 300
	04	IMA Giant
	01	Uhlmann UPS
	01	Uhlmann BEC 500, Double Blister-Line
BLISTER LINE (MANUAL/ STABILITY PACKAGING)	01	SEPHA EZ Blister
BOTTLE LINES (FULLY AUTOMATED)	03	Uhlmann IBC 123
		Uhlmann IBC 128
		Uhlmann IBC 150
BOTTLE LINE (MANUAL/ STABILITY PACKAGING)	01	King TC8
POWDER FILLING	01	Optima

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04 | QUALITY CONTROL



QUALITY CONTROL → QC Laboratory		
TYPE	AMOUNT	MACHINE
DISSOLUTION	10	Erweka and Agilent, Apparatus 1 AND 2 (EP/USP), manual sampling
	04	Sotax, Apparatus 1 AND 2 (EP/USP), semi-automated sampling
	01	Sotax, Apparatus 2 (EP/USP), fully-automated sampling
	03	Detection UV & LC UV
KARL FISCHER	02	Metrohm volumetric
	01	Metrohm volumetric + coulometric with oven
HPLC	45	Waters & Agilent
H-CLASS	10	Waters
GC	04	Agilent Liquid Injection / Headspace with FID
ICP - OES	01	Spectro Blue
TLC	04	Camag
IR	02	ThermoFischer Scientific IR

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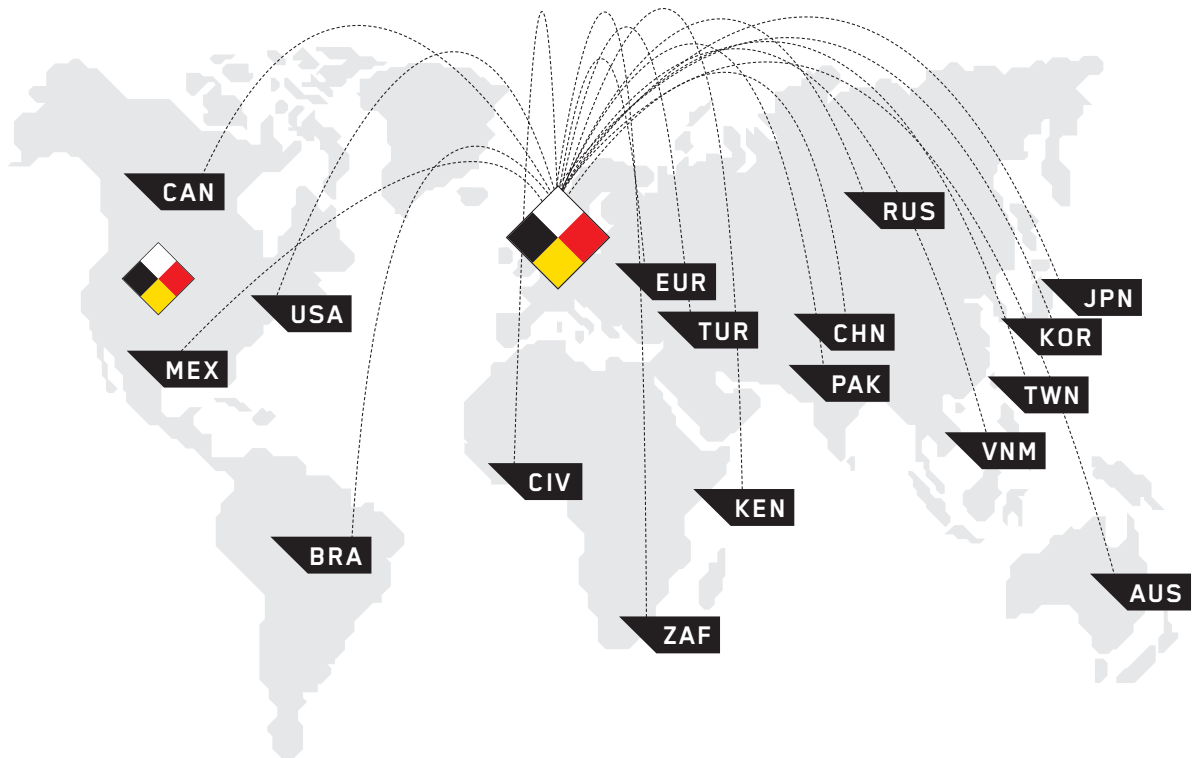
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GLEUGNER HELBACH DESIGN

Don't ask us what we have, tell us what you need.

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