Design Specification (DS)

Type:	ZSE 12 HP-PH - 40D
Machine number:	06080
Order number:	N-40136146
Customer:	Next Pharma

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1. Introduction / Aim of the document

This document describes the components and technical features of the pharma extrusion line ZSE 12 HP-PH - 40D.

2. Description of the machine

The machine number 06080 is a pharma extruder type ZSE 12 HP-PH - 40D which has a screw diameter of 12 mm and a process length of 40 D (in 5D increments).

The ZSE 12 HP-PH is a co-rotating intermeshing twin-screw extruder, designed for small scale extrusion in a range of 50 - 2000 g/h. It can be used for applications like hot melt extrusion or melt/wet granulation. The machine is made in stainless steel design and provides a D_o/D_i ratio which is in line with the Leistritz Pharma machines ZSE 18, 27, 40 and 50.
The base frame (made of stainless steel) is hosting the drive section, the process unit including material outlet device, cooling belt, electrical components and the interface of the control system.
The heating/cooling unit can be installed on a support at the frame or can be placed separately from the extruder.
The process unit (consisting of barrel and screws) has 9 zones, each of them is temperature controlled by PT100 element. The heating is done by heating cartridges and the cooling by water supplied by the heating/cooling unit. The process unit is designed as a compact barrel that can be split horizontally over the whole process length. This makes a process evaluation along the screws possible. Parts for heating and cooling of the zones are firmly embedded inside a C-profile which incorporates and tensions the process unit as well. Thus the assembly, disassembly and cleaning of the process unit can be done in a few steps. The whole process unit is covered with a stainless steel cover (=heating contact protection, not cooled).
The zones are always standard configurated:

Zone 9	Zone 8	Zone 7	Zone 6	Zone 5	Zone 4	Zone 3	Zone 2	Zone 1
0	1	1	1	1	1	1	1	E

(E = Einfüllen / Feeding, 1 = open 0 = closed)

By using the inserts, the zones can be adjusted in their function (e.g. from open to closed, from open for injecting liquid).
The extruder is supplied with one pair of segmented screws with a total length of 40 D. The process layout is flexible.
The following equipment is connected with the extruder:

- RX9100 Heating cooling unit zones BR-018-H1-K012-AE-FDA
-
- RX3000 Dosing unit MiniTwin MT-S-HD, Brabender
- RX4000 Liquid dosing Watson Marlow 120U/DV with pump head 114
- RX6000 Cooling belt MFB18-24VDC-BLE2-50.5-500, fedotec
-
-

The extruder together with the additional (peripheral) equipment is called extrusion line.

3. Hardware-Specification

3.1 Extruder

Num-ber	Drawing
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Num-ber	Description	Specification	Comment
--	Extruder ZSE12 HP-PH	Co-rotating twin screw extruder 50 – 2000 g/h (depends on the prod-uct) Hot melt extrusion T ≤ 250 °C	-

3.1.1 Screw

Num-ber	Description	Specification	Comment
3.1.1.1	Number	1 pair, length 40 D (incl. screw shaft and screw tip) 5D barrel length	Do/Di ratio 1.5
3.1.1.2	Screw elements diameter [mm]	11.85	-
3.1.1.3	Screw configuration	Modular, tailor made for customer process	-
3.1.1.4 3.1.1.5	Material screw elements	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.6	Material kneading blocks	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.7 3.1.1.8	Kneading element diame-ter [mm]	11.70	-
3.1.1.9	Material Distance element	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.10 3.1.1.11	Screw tips	Conical	-
3.1.1.12 3.1.1.13	Material screw tips	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
	Max. torque [Nm]	20	-
	Screw shaft sealing	3-times PTFE ring seal	-
	Screw shaft	30 ° (DIN 5480)	-
	Material screw shaft	1.4548	-

3.1.2 Barrel

Number	Drawing
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	Number	Description	Specification	Comment
		Number	8 Zones	-
3.1.2.1		Design	compact barrel that can be split horizontally over the whole process length installed in a C-Profile	-
			HP-bore whole 12,0 mm (H8) 5 x screw diameter (60 mm)	
3.1.2.2		Zone configuration	Zone 1: open, feed port	-
			Zone 2: open	Closed insert top
			Zone 3: open	Closed insert top
			Zone 4: open	Insert with bore top
			Zone 5: open	Closed insert top
3.1.2.3			Zone 6: open	Closed insert top
			Zone 7: open	Closed insert top, venting
			Zone 8: closed	Including closure
3.1.2.4		Material closing inserts for opened zones	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.5		Material feed port	1.4404 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.6				
3.1.2.7		Material closure caps with UNF bore	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.8		Material injection nozzle	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
		Seals with product contact	PTFE, at least FDA / EU conform incl. certificate	-
3.1.2.9		Temperature	Zone 1: 20-80 °C Zone 2: 20-160 °C* Zone 3-8: 20-250 °C	* Because of heat transfer between barrels the control accuracy of ± 2 °C cannot be guaranteed at temperature delta Δ T ≥ 60 °C.
3.1.2.10			accuracy of control ± 2°C	
3.1.2.11			Each zone is temperature controlled (please refer to sensors)	-
3.1.2.12		Temperature / heating	2 heating cartridges in each barrel (265 W)	-
3.1.2.13		Temperature / Cooling	Zone 1: connected to cooling water supply Zone 2-8: connected to cooling water supply RX9100	-
		Material barrel	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
		Extrusion height	1050 mm	-

3.1.3 Material discharge (zone 9)

	Number	Description	Specification	Comment
		Design	Die with integrated material outlet and with bore holes for melt temperature and melt pressure sensor	-
3.1.3.1		Temperature	Zone 9: 20-250 °C accuracy of control ± 10°C	-
			Zone is temperature controlled (please refer to sensors)	-
3.1.3.2		Temperature / heating	1 heating cartridge 100W	-
		Temperature / Cooling	Not connected to cooling water	-
3.1.3.3		Material	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.3.4				
3.1.3.5			Available sizes: 3.0 mm 2.5 mm 2.0 mm 1.8 mm 1.5 mm 1.2 mm 1.0 mm 0.8 mm 0.5 mm	
3.1.3.6		whole size of die		-

3.1.4 Feed

	Number	Description	Specification	Comment
3.1.4.1				
3.1.4.2		Connection	TC DIN DN 25 DIN 32676 Reihe A	-
		Seals with product contact	PTFE, FDA / EU conform incl. certificate	-

3.1.5 Drive

	Number	Description	Specification	Comment
		Motor	2.8 kW 2000 rpm	-
		Gear	10 – 1000 rpm	I = 2.5
			Frequency converter rotary encoder	-
3.1.5.1		Cooling	Water cooling	-
		System of protection	IP 64 (motor)	-
3.1.5.2 3.1.5.3 3.1.5.4		Gearbox	Safety clutch between motor and gear, automatic overload and under-load monitoring and shutdown	-
		Lubrication	Optileb GT 220 (H1 NSF No. 134148)	-
3.1.5.5		Transmission ratio	i = 2.5	-
3.1.5.6 3.1.5.7		Material motor and gear box	Painted with steel it, Installed in technical area	-

3.1.5.8

3.1.6 Base frame / surfaces

	Number	Description	Specification	Comment
3.1.5.1		Cooling cover	40D	No active cooling
			1.4301, polished with grain size 240 or better	-
3.1.5.2		Frame	1.4301, polished with grain size 240 or better	-
			movable, 4 wheels, lockable	-

3.1.7 Sensors

	Number	Description	Specification	Comment
3.1.7.1		Temperature sensor cylinder (no product contact)	PT100, class A	-
3.1.7.2			No certificated factory calibration available	-
			Integrated in cartridge heater	-
		Melt temperature (product contact)	PT 100 class A	-
			certificate factory calibration available	-
			2.4819 / HAS.C276	Measuring tip has contact to the product

Num-ber	Description	Specification	Comment
	Melt pressure (product contact)	diaphragm seal, 0 – 200 bar Performance level C	-
		½“-20 UNF	-
		1.4545 with GTP+ coating	GTP+ is a special coating from Gefran

3.1.8 General features

3.1.7.3

Num-ber	Description	Specification	Comment
	General design	Easy to access / to clean / to disinfect Low dead space Pipes and electric wire behind a cover	-
3.1.8.1	Surface (without product contact)	Easy to clean Ra ≤ 1,6 µm	-
3.1.8.2	Labelling	Sensors, pipes, wire, equipment is labelled according to PID	-
3.1.8.3	Extruder measurements	1600 (H) x 1200 (B) x 900 (T)	Without peripherals
3.1.8.4	Weight	~ 350 kg	-
3.1.8.5 3.1.8.6 3.1.8.7	Design connectors	GMP-Design Self-closing and quick disconnect couplings used for the cooling system Or if necessary TC-connectors DIN 32676 or Inch BS 4825, reducing different pipe classes	-
	Lubricants	NSF H1 certified	All used lubricants will be documented in a list during FAT

3.1.9 Media supply

Please refer to PID

3.1.10.1

3.1.10.2

3.1.10 Power supply and control

Num-ber	Description	Specification	Comment
	Supply	Main switch	At base frame
	Control cabinet	Integrated into the frame	-

Num-ber	Description	Specification	Comment
		DIN EN ISO 13850 DIN EN ISO 13849 parts 1 and 2 DIN EN 1037 DIN EN 61000-6-4, 6-2 Confirm to EN 60204 / DIN VDE 0113 part 1 DIN EN 60529 EMC 2014/30/EU	In addition to main guide lines for CE certificate
	Emergency stop	One switch at panel	-
	technology area	Similar to IP 54	No verification available / possible
3.1.10.3	Panel, visualization, pro-gramming	Please refer to HDS, SDS	-
3.1.10.4			
3.1.10.5			

3.2 Dosing unit – Volumetric powder feed (RX3000)

Number	Drawing
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	Number	Description	Specification	Comment
	--	Information	Brabender (DDW-)MT-S HD 1.0	-
3.2.1.1		Technical features	• Output depends on screws, Possible types: TC1212 (coarse screw), TC1204 (fine screw) • 1.0 dm3 • volumetric feeding • two feeding screw • horizontal agitator	-
3.2.1.2		Integration in extruder line	• Mounted on the extruder base frame. • The plug is connected behind the motor / gear technical area of the extruder. • Power supply from extruder	-
3.2.1.3		Surfaces with Product contact	Metallic parts AISI 316L, $R_a \leq 0{,}8$ µm 2.2 certificate or better	-
3.2.1.4			FDA/EU-Declaration of compliance for non-metallic material	
3.2.1.5		HMI	• Optional: Own operating panel • Feeder is controlled via the HMI of the extruder	-
		Signals to extruder HMI	• Profinet connection • Run / stop • General alarm • Setpoint • Actual speed value	

3.3 Cooling / heating unit (RX9100)

Number	Drawing
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Number	Description	Specification	Comment
--	Heating / Cooling unit	BR-018-H1-K12-AE-FDA	-
	Technical features	heat 1,5kW, cool 12kW max. 27 l/min, max. 4,5 bar	-
3.3.1.1	Integration in extruder line	• Mounted on a profile attached to the extruder frame. • The plug is connected on the motor side of the extruder. • Power supply from extruder	-
3.3.1.2	Surfaces with Product contact	-	-
3.3.1.3	HMI	with integrated local user interface	-
3.3.1.4 3.3.1.5	Signals to extruder HMI	• Profinet connection • Run / stop • General alarm • Setpoint • Actual temperature value	

3.4 Liquid dosing unit (RX4000)

Number	Drawing
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Number	Description	Specification	Comment
--	Watson Marlow tube case pump 120U/DV	0.1-200 rpm With pump head 114DV (flip-top single-channel pump head for continuous tubing): 0.002 ml/min - 190 ml/min	-
3.4.1.1	Technical features	Brushless DC motor Max. operating pressure: 2 bar Auto variable speed, variable speed 0.1rpm increments Analogue speed input; 4-20mA, 0-10V Tacho speed output; 0-5V	-
3.4.1.2	Integration in extruder line	• Mounted on the extruder base frame. • The plug is connected behind the motor / gear technical area of the extruder. • Power supply from extruder	-
3.4.1.3 3.4.1.4	Surfaces with Product contact	tubing	Smooth, wipe down case with no sharp edges to tear gloves and no bug traps. IP31 ingress protection
	HMI	with integrated local keypad	For remote and analogue control
3.4.1.5	Signals to extruder HMI	• 4-20 mA connection • Run / stop • Auto/Manuell • General alarm • Setpoint • Actual speed value	

3.5 Cooling Belt (RX6000)

Number	Drawing
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Number	Description	Specification	Comment
--	MFB18-24VDC-BLE2-50.5-500-SPEZ	Length 500 mm Belt width 45 mm	-
	Technical features	1-9.5 m/min Steady running No protective hood	-
3.5.1.1 3.5.1.2	Integration in extruder line	• is mounted on a table/profile, which is mounted on the extruder frame; the plug is connected to the plug panel on the outlet side. • Power supply from extruder	-
3.5.1.3	Surfaces with Product contact	FDA/EU-Declaration of compliance for non-metallic material and lubricants	-
3.5.1.4	HMI	Cooling belt is controlled via the HMI of the extruder; no own display	-
3.5.1.5	Signals to extruder HMI	• Frequency converter to ET200 • Run / stop • General alarm frequency converter • Setpoint Actual speed value	

3.6 Pelletizer (RX7000)

Number	Drawing
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Number	Description	Specification	Comment
--	IPS-SG-E MINI PHARMA	Throughput 4-15 kg/h Strand speed range 1-15 m/min Number of strands 1-3	-
	Technical features	Feed height ~ 1050 mm Outlet height ~ 800 mm 1-3 Strands	-
3.6.1.1 3.6.1.2	Integration in extruder line	• The device is freestanding; the plug is connected to the plug panel on the outlet side. • Power supply from extruder	
3.6.1.3	Cutting section	Housing Bed knife complete with cutting holder, cutting blade with 4 cutting edges, cutting gap is easily adjustable 1 cylindrical cutting rotor, 6 teeth Cutting width 0,04-0,06 mm	-
3.6.1.4	Draw-in section	Throat width 2,5 mm	-
3.6.1.5 3.6.1.6	Surfaces with Product contact	Metallic parts 1.4112, 1.4571 or equal FDA/EU-Declaration of compliance for non-metallic material and lubricants	-
	HMI	Pelletizer is controlled via the HMI of the extruder; no own display	No HMI
3.6.1.7	Signals to extruder HMI	• Frequency converter to ET200 • Run / stop • General alarm frequency converter • Setpoint infeed roll and cutting • Actual speed value infeed roll and cutting	

3.7 Universal device (RX10000): liquid pump

Number	Drawing
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Number	Description	Specification	Comment
--	Longer tube case pump (Drifton) L100-1S-2	0.01-10 rpm, 10.0-100.0 With pump head DMD15-13-B (single-channel pump head for continuous tubing, 2x3 rollers): 2 µl - 375 ml/min	-
	Technical features	Stepper motor Auto variable speed, variable speed 0.01 / 0.1rpm increments	-
3.7.1.1 3.7.1.2	Integration in extruder line	• Mounted on the extruder base frame. • The plug is connected behind the motor / gear technical area of the extruder. • Power supply from extruder	-
3.7.1.3	Surfaces with Product contact	Silicone tubing	Smooth, wipe down case with no sharp edges to tear gloves and no bug traps. IP31 ingress protection
3.7.1.4	HMI	with integrated local keypad (LCD)	For remote and analogue control
3.7.1.5	Signals to extruder HMI	To be defined; not integrated in standard software until now	

3.8 Drum cooler CCR 10/6

Number	Drawing
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	Number	Description	Specification	Comment
	--	CCR-10/06, BBA	0-1.9 rpm	-
		Technical features	Motor: 50 Hz; 1430 rpm; i=97.76:1 gear: i=15.5:1	-
3.8.1.1 3.8.1.2		Integration in extruder line	• is mounted on a table/profile, which is mounted on the extruder frame; the plug is connected to the plug panel on the outlet side. OR • Is mounted on a movable frame, which can be fixed at the extruder so that the complete extrusion line is movable. • Power supply from extruder	-
3.8.1.3		Surfaces with Product contact	Metallic parts AISI 316L, $R_a \leq 0{,}8$ µm 2.2 certificate or better FDA/EU-Declaration of compliance for non-metallic material	-
3.8.1.4		HMI	Cooling belt is controlled via the HMI of the extruder; no own display	-
3.8.1.5		Signals to extruder HMI	• Frequency converter to ET200 • Run / stop • General alarm frequency converter • Setpoint speed • Actual speed value	-

4. Conformities extruder

Number	Description	Specification	Comment
	Calibration	NO factory calibration certificate for temperature sensor cylinder and drive available! The cylinder / barrel temperature sensors will be checked (in house calibration) through FAT for at least two set points.	-
4.1.1.1		Factory Calibration certificate from the manufacturer for melt pressure and melt temperature available.	-
	Surfaces with product contact	EN 10204 factory certificate 2.2 for material and surfaces extruder and a list with all areas with product contact will be provided EN 10204 Certificate of Compliance with the Order 2.1 for melt pressure	3.1 certificate not available
4.1.1.2		FDA/EU conformity (at least) for gaskets / nonmetallic surfaces	-
4.1.1.3	Surfaces with no product contact	No conformity	-
4.1.1.4	Lubricants	NSF H1 conformity	-

A weld documentation is not part of the documentation, because there are no welds available at the extruder.

5. Environment

Number	Description	Specification	Comment
5.1.1.1			
5.1.1.2	Room	Minimum height 3 m Please refer to layout diagram	-
5.1.1.3			
	ATEX	Not intended for use in ATEX zone	-
	Underground (concrete)	Compressive strength of foundation min. 200 kN/m^2 concrete quality B25 or better	-

6. Abbreviation

Abkürzung	Beschreibung
ATEX	ATmosphères Explosibles
DS	Design Specification
FDA	U.S. Food & Drug Administration

Abkürzung	Beschreibung
GMP	Good manufacturing practice
HDS	Hardware Design Specification
HMI	Human machine interface
IP	IP code Protection class
NSF	National Sanitation Foundation
PID	Piping and Instrumentation Diagram
PTFE	Polytetrafluorethylen
SDS	Software Design Specification
TC	TriClamp
UNF	Unified National Fine Thread

7. Applicable Documents

Document Number	Version	Title
BZ 40136146PI010	A	PID Extruder
N 40136146-01	01	Order confirmation

8. Attachments

none

9. Appendix

none