Design-Specification (DS)

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Machine number:	06080
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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

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

3.1.1 Screw

Number	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.	Material screw elements	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.5.	Material kneading blocks	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.6.	Kneading element diameter [mm]	11.70	-
3.1.1.7.	Material Distance element	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.8.	Screw tips	Conical	-
3.1.1.9.	Material screw tips	1.4112, hardened R_a ≤ 0,8 µm (resp. R_z ≤ 4)	-
3.1.1.10.	Max. torque [Nm]	20	-
3.1.1.11.	Screw shaft sealing	3-times PTFE ring seal	-
3.1.1.12.	Screw shaft	30 ° (DIN 5480)	-
3.1.1.13.	Material screw shaft	1.4548	-

3.1.2 Barrel

Number	Description	Specification	Comment
3.1.2.1.	Number	8 Zones	-
3.1.2.2.	Design	C-Cylinder HP-bore whole 12,0 mm (H8) 5 x screw diameter (60 mm)	-
3.1.2.3.	Temperature	Zone 1: 20-80 °C Zone 2: 20-160 °C* Zone 3-8: 20-250 °C Measuring chain ± 2°C (under real conditions, e.g. product run	* Because of heat transfer between barrels the control accuracy of ± 2 °C cannot be guaranteed at temperature delta Δ T ≥ 80 °C.
		Temperature monitoring and control for each barrel	-
3.1.2.4.	Temperature / heating	2 heating cartridges each barrel (265 W)	-
3.1.2.5.	Temperature / Cooling	Heating/cooling-unit connection	-
3.1.2.6.	Assembling	Compact barrel with top and bottom part	-
3.1.2.7.	Material Cylinder	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.8.	Extrusion height	1050 mm	-
3.1.2.9.	Design	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
		Zone 6: open	Closed insert top
		Zone 7: open	Closed insert top, venting
		Zone 8: closed	Including closure
3.1.2.10.	Material closing inserts for opened zones	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.11.	Material feed port	1.4404 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.12.	Material closure caps with UNF bore	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.13.	Material injection nozzle	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-
3.1.2.14.	Seals with product contact	PTFE, at least FDA / EU conform incl. certificate	-

3.1.3 Material discharge

Number	Description	Specification	Comment
3.1.3.1.	Temperature / heating	1 heating cartridge 100W	-
3.1.3.2.	Temperature	Max. 250 °C Measuring chain ± 10°C (under real conditions, e.g. product run	No active cooling!
3.1.3.3.	Sensors	1 x Melt pressure	-
		1 x Melt temperature	-
3.1.3.4.	Die head	LSK12 (Material outlet and die)	1 x 0.8 mm 1 x 1.8 mm 1 x 3 mm
3.1.3.5.	Material Die head	1.4112 $R_a \leq 0{,}8$ µm (resp. $R_z \leq 4$)	-

3.1.4 Feed

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

3.1.5 Drive

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

3.1.6 Base frame / surfaces

Number	Description	Specification	Comment
3.1.6.1.	Cooling cover	40D	No active cooling
		1.4301, polished with grain size 240 or better	-
3.1.6.2.	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	-
		No certificated factory calibration available	-
		Integrated in cartridge heater	-
3.1.7.2.	Melt temperature (product contact)	PT 100 class A	-
		certificate factory calibration available	-
		2.4819 / HAST.C276	Measuring tip has contact to the product
3.1.7.3.	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

Number	Description	Specification	Comment
3.1.8.1.	General design	Easy to access / to clean / to disinfect Low dead space Pipes and electric wire behind a cover	-
3.1.8.2.	Surface (without product contact)	Easy to clean Ra ≤ 1,6 µm	-
3.1.8.3.	Labelling	Sensors, pipes, wire, equipment is labelled according to PID	-
3.1.8.4.	Extruder measurements	1600 (H) x 1200 (B) x 900 (T)	Without peripherals
3.1.8.5.	Weight	~ 350 kg	-
3.1.8.6.	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	-
3.1.8.7.	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 Power supply and control

Number	Description	Specification	Comment
3.1.10.1.	Supply	Main switch	At base frame
3.1.10.2.	Control cabinet	Integrated in the frame	-
		Confirm to EN 60204 / DIN VDE 0113 part 1 DIN EN ISO 13849 parts 1 and 2, Directive 2014/35/EU, EMC 2014/30/EU	-
3.1.10.3.	Emergency stop	One switch at panel	-
3.1.10.4.	technology area	Similar to IP 54	No verification available / possible
3.1.10.5.	Panel, visualization, programming	Please refer to HDS, SDS	-

3.2 Dosing unit – Volumetric powder feed (RX3000)

Number	Description	Specification	Comment
--	MT-S HD 1.0	Depends on screw: TC1212: 0.28 – 5. 60 kg/h TC1204: 0.06 – 1.26 kg/h 1.0 dm3	Theoretical values at 100% screw filling level and motor speed. Depending on the flow properties of the bulk material, the filling level can drop by up to 50%.
3.2.1.1.	Technical features	volumetric feeding two feeding screw types TC1212, TC1204 horizontal agitator On extruder base frame	-
3.2.1.2.	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	-
3.2.1.3.	HMI	Feeder is controlled via the HMI of the extruder	-

3.3 Cooling / heating unit (RX9100)

Number	Description	Specification	Comment
--	Heating / Cooling unit	BR-018-H1-K12-AE-FDA	-
3.3.1.1.	Technical features	heat 1,5kW, cool 12kW max. 27 l/min, max. 4,5 bar	-
3.3.1.2.	Surfaces with Product contact	-	-
3.3.1.3.	HMI	with integrated local user interface	-

3.4 Liquid dosing unit (RX4000)

Number	Description	Specification	Comment
--	Watson Marlow tube case pump 120U/DV	0.1-200 rpm With pump head 114DV (flip-top single-channel pumphead 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.	Surfaces with Product contact	tubing	Smooth, wipe down case with no sharp edges to tear gloves and no bug traps. IP31 ingress protection
3.4.1.3.	HMI	with integrated local keypad	For remote and analogue control

3.5 Cooling Belt (RX6000)

Number	Description	Specification	Comment
--	MFB18-24VDC-BLE2-50.5-500-SPEZ	Length 500 mm Belt width 45 mm	-
3.5.1.1.	Technical features	1-9.5 m/min Steady running No protective hood	-
3.5.1.2.	Surfaces with Product contact	FDA/EU-Declaration of compliance for non-metallic material and lubricants	-
3.5.1.3.	HMI	Cooling belt is controlled via the HMI of the extruder	-

4. Conformities extruder

Number	Description	Specification	Comment
4.1.1.1.	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.	-
		Factory Calibration certificate from the manufacturer for melt pressure and melt temperature available.	-
4.1.1.2.	Surfaces with product contact	EN 10204 factory certificate 2.2 for material and surfaces 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
		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.	Room	Minimum height 3 m Please refer to layout diagram	-
5.1.1.2.	ATEX	Not intended for use in ATEX zone	-
5.1.1.3.	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
GMP	Good manufacturing practice
HDS	Hardware Design Specification
HMI	Human machine interface
IP	IP code Protection class
NSF	National Sanitation Foundation

Abkürzung	Beschreibung
PID	Piping and Instrumentation Diagram
PTFE	Polytetrafluorethylen
SDS	Software Design Spezification
TC	TriClamp
UNF	Unified National Fine Thread

7. Applicable Documents

Document Number	Version	Title
BZ 40136146PI010	C	PID Extruder
N 40136146-01	02	Order confirmation

8. Attachments

none

9. Appendix

none