Functional-Design-Specification (FDS)

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

Change history:

Date	Version	Change/Addition
21.08.2025	1.0	Final

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1. Introduction / Aim of the document

This document describes functional design of the software installed on an IPC 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 ZSE12 is a co-rotating intermeshing twin screw extruder. The processing system is modular and consists of individual barrel segments in a compact cylinder. Each barrel segment has its own heating/cooling temperature control with PT100 sensors sending the measured value to the controller.
The system uses heating cartridges combined with water cooling via bores in the barrel supplied by the cooling water media supply from the customer.

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. Principle description of the software behavior

The equipment / peripheries are controlled by an automation system comprising of a Siemens S7 PLC (TIA Portal) and a COPA DATA SCADA system (zenon), which is 21 CFR Part 11 / EU GMP annex 11 compliant. The zenon SCADA system is installed on an IPC with all necessary software packages and licenses by Leistritz.

The following peripheries have their own control panel:

- RX9100
- RX4000

At these panels it is possible to set values, read errors / alarms and set settings. The description of the alarms and values, which were send to the extruder SCADA system, are described in the alarm list and the unit list.

Note: In principle, a panel called OP S can also be provided for dosing unit RX3000. However, this is not included in the scope of delivery.

For detailed description of the software structure, connections and functions please refer to SDS and HDS.

3.1 Interlock Modes

The system differentiates two interlocking modes, “Cleaning” and “Production”. An active interlock means, that a component is locked and will be directly switched off. A switching on of an interlocked unit is not possible. The interlock mode does not affect alarms and warnings, they are generated at any time in accordance with the alarm list.
All interlocks are described in the document Interlocking matrix.

Cleaning mode:
This interlocking mode is used for cleaning and maintenance of the extruder. Almost all components could be switched on and off independently. Only safety relevant interlocks are active.

Production mode:
This mode is used for manufacturing of product / batch production. The switching on / off of the components will be controlled in a logical way. For example, the dosing could only be switched on, if the main drive is running. Additionally, the safety relevant interlocks are active.

3.2 Operating modes

The individual components of the system can be operated either in manual mode or in automatic mode.

Manual mode:
During the manual mode the operator can control the extruder units manually. To do this, he must set the individual components to manual mode via the respective faceplate. He can switch units on or off and can change set values.
In manual operation (e.g. for a test operation) of the Extruder it is not possible to record a manual batch.

Automatic mode:
The automatic mode simplifies the operating of the extruder and takes care of the start-up sequence for the operators. During automatic mode, the extruder components are controlled automatically by the extruder PLC. Set points are set based on the recipe parameters and control is performed according to the production sequence. At sequence start the operator has to set all extruder components into automatic mode. A subsequent switchover of a component to manual mode is permitted and is recorded in the audit trail.
After the start-up steps the sequence goes into the production step and starts the batch recording.

Pause:
During the start-up steps, the sequence can be switched into “Auto Pause” by an operator. No units are switched off by this operation. Only the switching into next step will be interrupted (e.g. the jump from Start-up 1 to Start-up 2). Already started timers will be stopped by the “Auto Pause” function.

Auto Emptying:
The system jumps from the active step to the “Empty Step”. This means that the dosing units will be switched off. The main drive will be still running. The Empty step ends by a torque value of the main drive lower the LOLO value for the extruder load or a time step.
Also, the switch-off of the main drive will finish the “Empty Step”. Alarms of the category “Error Abort” (see following chapter) will also end the sequence via the “Empty Step”.

3.3 Emergency stop behavior

After an emergency stop is pressed (regardless at which device of the extrusion line), the main drive, the heat exchanger, the dosing unit and the drum cooler will be switched off. The PLC and the SCADA system are left on.
A corresponding message will be generated by the SCADA system and will be shown on the visualization.

3.4 Fault behavior

The system alarms are divided in two categories: “Warning” and “Abort”. In interlocking mode “Production”, all lined up alarms will be signaled over flashlight and horn in addition to the basic display on the HMI.
In cleaning mode, the horn will be disabled.
All alarms and warnings and the corresponding activation conditions are defined in the document alarm list.

Warning:
A warning message has no effect to the process. The operator will only be informed over the issue. No units will be switched off with a warning message.

Alarm / error abort:
This fault is so critical that the system must be switched into a predefined state. This also includes communication failure or the pressing of an emergency stop. If an “Error Abort” fault occurs with active automatic sequence, the system leaves the active step and switches into the "Empty" step. If possible, the emptying of the extruder will be done automatically. After that, the units will be switched off.
If the main drive is stopped by the alarm, the emptying of the Extruder is not possible. The sequence goes directly in initial state.

3.5 Batch run / batch production

The batch run will be controlled through an automatic sequence by a recipe. This sequence triggers all units and drives. The sequence of the extruder runs only in single batch operation.
(please refer to production mode)

Batch start:
After heating up of the extruder and the startup steps in automatic mode, a popup for input of the batch data will be displayed. On this popup the operator must enter the batch name, product name and product number for the batch run and he must push the button “OK” to start the “Production” step.
With start of the automatic step “Production” a batch recording will be started.

Batch end:
The automatic process will be finished via “Empty” step. The Empty step ends by a torque value of the main drive lower the LOLO value for the extruder load or a time step.
The “Empty” step could be reached via error abort or via operator switch off. With end of the automatic sequence, the operator has to end the batch recording manually.

4. Data integrity

4.1 Data collecting and archiving

For collecting and archiving of values zenon integrated reporting system will be used. All recorded values can be viewed and selected on a trend picture on the SCADA-System.
The in zenon integrated reporting system supports with the documentation, analyzation and presentation of process data, based on online- and historical data.
The report viewer is used for displaying and printing batch records, recipe-, alarm and audit trail data.
The report definition file, existing of several Datasets is created and configured in the editor and cannot be changed during runtime.

4.2 Audit trail

For the data integrity an Audit-Trail will be used in the SCADA-System.
All events will be stored.
The audit trail can be used to trace, log and archive who set/did what in the software and when including set values.

4.3 Access protection

The zenon user administration has been created to meet all necessary requirements of the FDA (Food and Drug Administration, 21 CFR Part 11) and EU GMP annex 11.
User login is to be made by the login button in the head region of the screen.
After entering the username and the personnel password access will be allowed according to the existing user rights of the SCADA.
The user management concept defines which different users can receive which different rights for user access, user level and function permissions.
User and User groups can be managed.
The desired password rules (password length, life etc.) are binding to all users.
For each user different access privileges can be assigned. In this project 9 different access rights are available, please refer to SDS for description of the access rights.

5. Abbreviation

Abkürzung	Beschreibung
ARL	Alarm List
FDA	U.S. Food & Drug Administration
FDS	Functional Design Specification
GMP	Good manufacturing practice
HDS	Hardware dsign specification
HMI	Human machine interface
LMX	Interlock Matrix
LOLO	Lowlow (alarm)
PLC	Programmable Logic Controller
SCADA	Supervisory Control and Data Acquisition
SDS	Software design specification
TIA	Totally Integrated Automation Portal
UNL	Unit List

6. Applicable Documents

Document Number	Version	Title
BZ 40136146PI010	A	PID Extruder 06080
N 40136146-01	01	Order confirmation
ARL_6080	01	Alarm list Pharma Extrusion line ZSE 12 HP-PH - 40D, machine number 06080
UNL_6080	01	Unit list Pharma Extrusion line ZSE 12 HP-PH - 40D, machine number 06080
LMX_6080	01	Interlock Matrix Pharma Extrusion line ZSE 12 HP-PH - 40D, machine number 06080
SDS_6080	01	SDS Pharma Extrusion line ZSE 12 HP-PH - 40D, machine number 06080
HDS_6080	01	HDS Pharma Extrusion line ZSE 12 HP-PH - 40D, machine number 06080

7. Attachments

none

8. Appendix

Schematical overview automatic sequence

Appendix 1:

How to run a sequence

In Automatic

Select the production mode on the F_Sequence



Click the „AllComponenInAuto“ button (*)



Start the sequence by clicking the „Start“ buttion in the AutomaticSequence



In step 2, enter the batch data (all fields miust be filled, and special characters should not be used)

In step 3, select and load a recipe on the recipe manager screen (**)



From this point onward, the system operates acording to the logic and the values of the recipe

In step 12, the produccion starts and also the record of a protocol

Once the sequence is completed, it returns to Step 0, where the batch must be closed by clicking the "EndBatch" button (***)



A window will then appear, where the batch must be selected and confirmed by pressing "OK"

(*) If this step is not performed and the main drive cannot be controlled by the system, the sequence will stuck at step 6, as it waits for the extrude to be active before moving to the next step.
If this has been forgotten, the button must be pressed.
(**) To save time, perform this action before starting the sequence.
(***) The batch does not close automatically when the sequence reaches position 0.
The batch MUST BE CLOSED MANUALLY before starting another batch.

In Manual

Select the production mode on the F_Sequence



Click the „AllComponenInManual“ button (!)



Start the sequence by clicking the „Start“ buttion in the ManualSequence



Enter the batch data (all fields miust be filled, and special characters should not be used)

From this point onward, the developer can start/ stop and set values manually and everything will be recorded in a protocol (!!)

Once the developer is done testing,the batch can be closed by clicking the "EndBatch" button (!!!)



A window will then appear, where the batch must be selected and confirmed by pressing "OK"

(!) With the system in automatic mode, a recipe can be loaded so that the devices start with a predefined value. Afterwards, the system can be switched to manual mode, allowing individual components to be turned on/off as needed.
(!!) There are no predefined steps or timing set by the system. The operator decides what to do, when to do it, and how to proceed.
(!!!) The batch does not close automatically when the sequence reaches position 0.
The batch MUST BE CLOSED MANUALLY before starting another batch.