

# VALIDATION & QUALIFICATION PACKAGES

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# PACKAGES

**Qualification and Validation: modular packages of documentation**

- Enflex has a **specific team** dedicated to the creation of **validation** documentation and the **qualification of equipment** for GMP environments
- We can also count on the support of **external consulting firms** with extensive experience in the pharmaceutical sector
- We have designed our Validation & Qualification documents in **modular packages**, to meet the simplest to the most complex needs



**Basic**

Installation Qualification (IQ)  
Operational Qualification (OQ)



**Plus**

Pharma Factory Acceptance Test (FAT)  
Site Acceptance Test (SAT)  
Installation Qualification (IQ)  
Operational Qualification (OQ)



**Premium**

Qualification Plan (QP)  
Pharma Risk Assessment (RA)  
Pharma Factory Acceptance Test (FAT)  
Site Acceptance Test (SAT)  
Installation Qualification (IQ)  
Operational Qualification (OQ)



**Elite**

Qualification Plan (QP)  
Pharma Risk Assessment (RA)  
Functional Designs Specifications (FDS)  
Hardware Designs Specifications (HDS)  
Software Designs Specifications (SDS)  
Design Qualification (DQ)  
Pharma Factory Acceptance Test (FAT)  
Site Acceptance Test (SAT)  
Installation Qualification (IQ)  
Operational Qualification (OQ)




# Qualification Plan (QP)

The purpose of the Qualification Plan (QP) is to provide and define the qualification activities that will be performed during project execution, the responsibilities that correspond to the staff involved and the procedures that must be carried out.

The following information is detailed in the QP:

- Project qualification strategy
- Project qualification documentation structure
- List of qualification tests.
- Methodology (management of deviations and change controls)
- Responsibilities matrix


	<b>QUALIFICATION PLAN (QP)</b> PH-28 DX- Customer Name	<b>QP_C004.01793</b>	
		<small>Edition</small> 03 April 2023	<small>Version</small> 1.0

**QUALIFICATION PLAN (QP)**

<b>Equipment:</b>	Horizontal Form Fill Seal Machine
<b>Type of equipment:</b>	PH-28 DX
<b>Serial Number</b>	#02204EF001
<b>Customer:</b>	Customer Name
<b>Document Reference:</b>	QP_C004.01793
<b>Version:</b>	1.0
<b>Pages:</b>	16

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	<b>QUALIFICATION PLAN (QP)</b> PH-28 DX- Customer Name	<b>QP_C004.01793</b>	
		<small>Edition</small> 03 April 2023	<small>Version</small> 1.0

**8.- PROJECT ACTIVITIES**

**8.1.- Project Start-up**

The preliminary examination of the project is the first activity to develop and allow the project start-up. The contractual documents and the Customer requirements (URS) are examined to evaluate the feasibility of the project by performing a F&S/Gap analysis.

Once confirmed the project feasibility, a Kick-off meeting is scheduled to define the project team and to discuss the conceptual design, the preliminary configuration and features of the equipment as well as the crucial economic parameters for overall project evaluation and successive decisions taking.

**8.2.- Layout Design**

The project design development starts with the definition of the machine basic configuration. The initial project specifications are represented in the layout technical drawing that is issued and forwarded to the Customer for approval.

**8.3.- Design Documentation Plan**

All the documents to be issued during the design phase will be available in the internal project repository in compliance with the Volpak Quality procedures.

Documents submitted to the Customer are managed by the Project Manager only. He provides the link between Volpak and Customer regarding the documentation, and he will inform the stakeholders in case of information to add, to modify or to delete.

The project documentation, as presented in the following table, is supplied in according to the timing reported by the planned GANTT. These dates are subject to change with the agreement of the Customer.

Document	Reference	Issued by	Reviewed by	Approved by
Qualification Plan (QP)	QP_C004.01793	Validation Specialist	Project Manager Mechanical Engineering Supervisor Quality Manager	Customer
Risk Assessment (RA)	RA_C004.01793	Validation Specialist	Mechanical Engineering Supervisor Quality Manager	Customer
Functional Design Specifications (FDS)	FDS_C004.01793	Engineering	Validation Specialist Mechanical Engineering Supervisor Quality Manager	Customer
Hardware Design Specifications (HDS)	HDS_C004.01793	Engineering	Validation Specialist Mechanical Engineering Supervisor Quality Manager	Customer
Software Design Specifications (SDS)	SDS_C004.01793	Engineering	Validation Specialist Mechanical Engineering Supervisor Quality Manager	Customer
Design Qualification (DQ)	DQ_C004.01793	Validation Specialist	Mechanical Engineering Supervisor Quality Manager	Customer

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# Pharma Risk Analysis (RA)

Risk analysis methodology enables assessment of equipment features from the perspective of GMP compliance. Assessment is carried out on all aspects that may affect product quality, patient safety and/or data integrity.

The FMEA (Failure Mode and Effects Analysis) method is used to classify the various parts of the machine, analyse potential failures and their consequences, assess the likelihood and detectability of the failure and the severity of the consequence. These three assessments reveal a risk rate which, if properly tabulated, can indicate the qualification actions required to mitigate the risk.

VOLPAK

a harsco company

RISK ASSESSMENT (RA)

PH-28 DX- Customer Name

RA\_C004.01793

Edition

03 April 2023

Version

1.0

RISK ASSESSMENT (RA)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	RA_C004.01793
Version:	1.0
Pages:	75

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VOLPAK

a harsco company

RISK ASSESSMENT (RA)

PH-28 DX- Customer Name

RA\_C004.01793

Edition

03 April 2023

Version

1.0

6.3.- Risk Evaluation:

Combining the probability of failure with severity and detectability in the following table, GMP- criticality is determined:

Probability	Severity	GMP- Criticality		
		Detectability		
		Low	Medium	High
High	High	High	High	Medium
	Medium	High	High	Medium
	Low	High	Medium	Low
Medium	High	High	High	Medium
	Medium	High	Medium	Low
	Low	Medium	Low	Low
Low	High	High	Medium	Low
	Medium	Medium	Low	Low
	Low	Medium	Low	Low

The value of GMP- Criticality obtained serves to focus resources in areas where the company is most exposed to risks. These should be considered in relation to the risk tolerance. Its classification will determine the need for a specific qualification test.

GMP- Criticality	Description
High (H)	A specific test is needed.
Medium (M)	A generic test is sufficient.
Low (L)	A qualification test is not needed.

Mitigation Analysis: This analysis evaluates the level of risk for each item considering its severity, probability and detectability considering the application of the measures defined to mitigate the risk.

GMP- Criticality (After Qualification)	Description
High (H)	The client must switch to a different procedure or machine to avoid/mitigate this risk.
Medium (M)	The client must monitor this risk periodically.
Low (L)	The risk is under control.

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RISK ASSESSMENT (RA)

PH-28 DX- Customer Name

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Edition

03 April 2023

Version

1.0

7.- RISK ASSESSMENT TABLE

No.	Item	Risk	Assessment				Measures	Risk Assessment considering defined measures			
			Probability	Severity	Detectability	GMP- criticality		Probability	Severity	Detectability	GMP- criticality
1.	Documentation	<div>Potential failure:</div> <div>System documentation is not available, or the documentation available does not represent the actual situation.</div> <div>Source of failure:</div> <div>The documentation corresponding to the system has not been generated.</div> <div>Failure Consequences:</div> <div>The system is not properly documented. Regulatory breach. It can affect operation and quality, and cause errors in maintenance tasks.</div>	M	H	M	H	<div>[K2] Check the availability of the documentation associated to the system.</div> <div>[K2] Check that the characteristics of the different system elements correspond with the available documentation.</div> <div>[K2] Check that the available plans conform to the actual installation.</div>	L	H	H	L

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# Functional and Design Specifications (FDS)

This document is prepared during the design phase and approved by the customer once the phase has been completed.


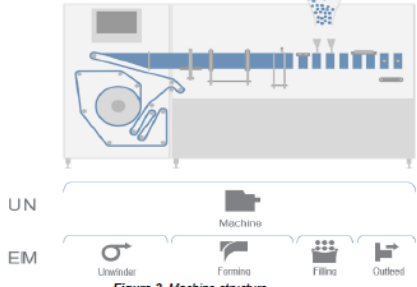
The FDS are set forth in two documents:

- FS: Functional Specifications –This document describes the functional design of the equipment.
- DS: Design Specifications –This document describes the mechanical, electric and programming design of the equipment.

	FUNCTIONAL DESIGN SPECIFICATIONS (FDS) PH- 28 DX- Customer Name	<i>FDS_C004.01796</i> Edition 03 April 2023	Version 1.0
FUNCTIONAL DESIGN SPECIFICATIONS (FDS)			
Equipment:	Horizontal Form Fill Seal Machine		
Type of equipment:	PH- 28 DX		
Serial Number	#02204EF001		
Customer:	Customer Name		
Document Reference:	FDS_C004.01796		
Version:	1.0		
Pages:	23		

FK2 03.01 – Functional Design Specifications ed 01

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	FUNCTIONAL DESIGN SPECIFICATIONS (FDS) PH- 28 DX- Customer Name	<i>FDS_C004.01796</i> Edition 03 April 2023	Version 1.0
6.- FUNCTIONAL SPECIFICATION			
6.1.- General Description			
The horizontal form fill seal machine HFFS PH-28 DX is a machine 4-side seal flat pouches, operating from a single reel of flexible thermo-sealable material, forming the pouch, filling it with product according to the provided dosing system, and sealing the pouch at the top. The equipment is constructed as a compact unit, reducing the area it occupies in the room.			
The machine is built applying advanced technologies, which have been developed through VOLPAK's experience, using materials and components of high quality, that cannot interact with, react with, or absorb the pharmaceutical product being packed, and, neither can release any substances or particles that can affect this pharmaceutical product.			
The machine frame and covers are made of carbon steel with special paint (steel-it) and the other parts and external mechanism of the filling station are made of nickel coated carbon steel and aluminium hard chromium coating.			
6.1.1.- Machine structure			
The machine structure can be divided in different modules or stations (see Figure 3):			
			
Figure 3. Machine structure			
1. Machine Unite (UN):			
a. Film line: The front part of the machine where all the operations to form and fill the pouches are carried out.			
b. Main shaft: At the rear part of the machine are the mechanisms that make the machine work, the main shaft.			
2. Unwinder			
It is designed to support reels with a maximum diameter of 600 mm and mechanically unrolled reel.			
3. Forming			
Area where the sachet is made, making the vertical seals and bottom seal.			
4. Filling			
Area through which the sachet passes. It is transported by the trolley mechanism, by the different stations, top opening, dosing and upper sealing.			

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# Hardware Design Specifications (HDS) & Software Design Specifications (SDS)

**The HDS and SDS are the documents that detail the design of the equipment's computer and control system.**

These documents serve to complement the FDS by including specific details of automation design, such as:


- Architecture
- User interface (HMI, SCADA, pushbuttons, printers)
- PLC
- Inputs and outputs
- Sensors and instruments
- Safety devices
- Power supply systems
- Communications (network)
- Operation, shut down and emergency modes
- Servomotor controls
- Alarms
- Access levels
- Critical parameters and configurable parameters (setpoints)
- Electronic records and Audit Trail

 a world company	SOFTWARE DESIGN SPECIFICATIONS (SDS)	SDS_C004.01793	
	PH-28 DX- Customer Name	Edition 03 April 2023	Version 1.0

## SOFTWARE DESIGN SPECIFICATIONS (SDS)

<b>Equipment:</b>	Horizontal Form Fill Seal Machine
<b>Type of equipment:</b>	PH-28 DX
<b>Serial Number</b>	#02204EF001
<b>Customer:</b>	Customer Name
<b>Document Reference:</b>	SDS_C004.01793
<b>Version:</b>	1.0
<b>Pages:</b>	32

FDZ 00.01 – Software Design Specifications ed 0

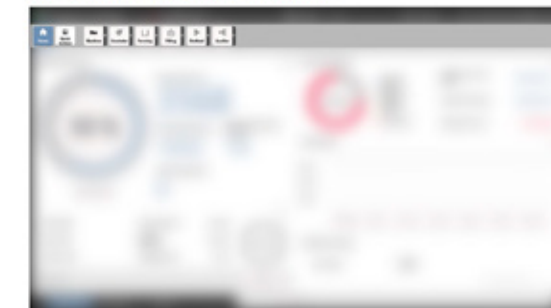
 <b>VOLPAK</b> <small>a world company</small>	<b>SOFTWARE DESIGN SPECIFICATIONS (SDS)</b> <b>PN-28 DX- Customer Name</b>		<b>SDS_C004.0179</b>	
			<small>Edition</small> <b>03 April 2023</b>	<small>Version</small> <b>1.0</b>

### 6.2.3.- Right sidebar

This menu is shown by clicking on the logo icon, and it displays a sidebar on the right side of the screen with the buttons for: Debugging tools, closing applications and shut down the system.

#### 6.2.4. Process navigation

The process navigation bar is located under the top bar, and contains the accesses to the different screens that allow the user to configure and manage the operation of the machine.



In this menu, all configurations and operations are organized in a structure of different access based on PackML standard.

In the first level the machine is decomposed in different Equipment Modules (EM):

- Machine
- Unwinder
- Forming
- Filling
- Outfeed

In the second level (inside each EM), there are all Control Modules (CM) that represent specific elements of the machine. All CM corresponds to the machine's software modules list.



An example is the CM vertical sealers of the machine, which is located inside Forming EM.

- There is also two button that give access to:
- Home screen
  - Quick actions screen

FR2 03 01 - Software Design Specifications ed 01

VOLPAK	SOFTWARE DESIGN SPECIFICATIONS (SDS)	SDS_C004.01793	
	PH 28 DX - Customer Name	03 April 2023	1.0

## list

	DESCRIPTION
ignation	Menu
creens	Description
Production Home (for production mode) Manual Home (for manual mode)	Production: Main screen of machine information, Status and statistics. Manual: Main screen that provide access to all manual actions.
Quick actions: Pouch adjustment	Most common functions for production
Quick actions: Sealers monitor	Overview of all sealers
E 	General parameters or functions
creens	Description
Shift register	Pouch information tracking
Safety	Safety elements information (Doors and E-Stops)
Tele-service	External assistance communications status
Batch Control	Batch production parameters, status, and control
CFR Control	21 CFR part 11 options
r 	Station and devices related to material unwinder zone
creens	Description
Coding	Code/Barcode printer
Reel Unwinder	Unwinder parameters (e.g., end of reel)
Splicer Tag Detection	Reel connection mark detection

ware Design Specifications ed 01

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 a vesco company	<b>HARDWARE DESIGN SPECIFICATIONS (HDS)</b> <b>PH-28 DX- Customer Name</b>	<b>HDS-004-0179</b>
		Edition 03 April 2023

### HARDWARE DESIGN SPECIFICATIONS (HDS)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DIX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	HDS_C004.01793
Version:	1.0
Pages:	22

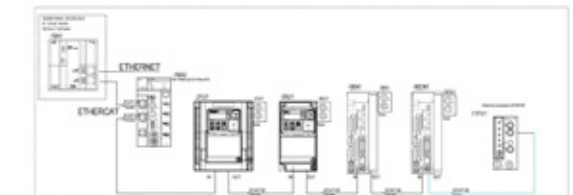
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 VOLPAK <small>a family company</small>	<b>HARDWARE DESIGN SPECIFICATIONS (HDS)</b> PH 28 DX - Customer Name	<b>HDS_C004.01793</b>	
		Edition 02 April 2022	Revision 1.0

### 5.2.1. Internal interfaces

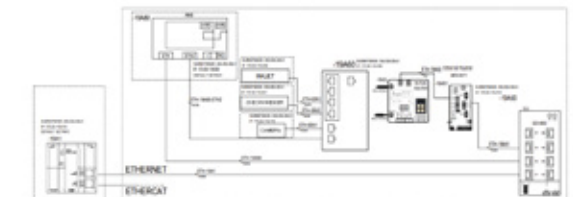
The internal interfaces will allow the control system to send and process data between the different components of the system architecture such as remote I/O, pneumatic valves, servomotors, etc. This interface is based on Omron Ethercat.



**Figure 1. Internal interfaces**

### 5.2.2.- External Interfaces

The external interfaces will allow the control system to capture external data from various sources and to provide visualization to the HMI. This interface is ethernet based.



**Figure 2. External interfaces**

Element	IP	Mask	Gateway
PLC	172.20.119.10	255.255.255.0	N.A.
PLM	172.20.119.20	255.255.255.0	N.A.

PAC-03.04 - Hardware Design Specifications ed 01


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# Design Qualification (DQ) Protocol

The purpose of DQ is to verify that the points described in the design documentation (FDS, SDS, HDS) comply with the requirements set out in the URS and/or offer.

DQ execution and conformity mark the starting point for equipment construction.


 <small>a coxsa company</small>	DESIGN QUALIFICATION (DQ) PH-28 DX- Customer Name	DQ_ C004.01793	
		<small>Edition</small> 03 April 2023	<small>Version</small> 1.0

DESIGN QUALIFICATION (DQ)

Equipment:	Horizontal Form Fill Seal Machine
Type of equipment:	PH-28 DX
Serial Number	#02204EF001
Customer:	Customer Name
Document Reference:	DQ_ C004.01793
Version:	1.0
Pages:	24

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 <small>a coxsa company</small>	DESIGN QUALIFICATION (DQ) PH-28 DX- Customer Name	DQ_ C004.01793	
		<small>Edition</small> 03 April 2023	<small>Version</small> 1.0

6.- METHODOLOGY

This protocol describes a set of tests that demonstrate that the system and its components have been correctly designed, according to the manufacturer's specifications and the requirements of the User Requirement Specifications.

This document comprises both the Design Qualification protocol and report. The protocol must be fully authorised prior to commencing the report.

6.1.- Personnel

All persons responsible for performing tests will be identified in section 7. 'Registry of the personnel involved in the qualification'.

6.2.- Test contents

The DQ is carried out reviewing the design documentation and verifying the traceability of each user requirement with the adopted design solution.

The instructions to fill in the tables of DQ test are shown below:

Column	Instructions
URS ID	In this column the ID of the requirement is indicated as described in the URS document.
URS Description	In this column the description of the requirement is indicated as described in the URS document.
Ref FDS/ Technical Documentation	In this column it is indicated the ID of the corresponding technical/FDS documentation.
Acceptable Y/N	In this column it is reported whether the requirement has been satisfied or not. <ul style="list-style-type: none"><li>Enter 'YES' if the requirement is met and the step completed successfully.</li><li>Enter 'NO' if the Requirement is not met and the step could not be completed successfully.</li></ul> In case of a 'NO' entry occurred for a MUST requirement, provide details in the 'Deviation List' (see section 6.4 Handling of Deviations.  If the requirements were not fully met since they needed to be tested during FAT, SAT, IQ or OQ, an entry of 'YES' may be made also if the step is not completely successfully. The details of the activity to be done in order to satisfy the Requirement will be provided in column 'Note'.
Note	Each observation noted during the DQ must be reported in the relevant section 'Notes'. Any actions necessary to correctly address the observations must be recorded in the 'Deviation List'. If the requirements are not met, it is necessary to insert a justification and evaluate the management of any gaps in the system. In this column it is also reported a brief description of the activities should be done later in case of requirement not verifiable during DQ.

To successfully complete the DQ activities, the qualification personnel must execute the tests required in this protocol and report the results in the dedicated section of the document. The conclusion of the test will be marked with an "X" following the criteria shown below:

PK2 05.01 – Design Qualification ed. 01

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# Pharma Factory Acceptance Test (FAT) Protocol

The purpose of the Pharma FAT protocol is to verify that the machine has been installed and is operating according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These verifications are carried out in the Volpak plant with the aim of accepting the equipment before it is delivered to the customer's facilities. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.

**The following tests are included in the FAT protocol:**

- Document verification (Draft version)
  - Conformity of the plans (Draft version)
  - Conformity of the components
  - Verification of the parts in contact with the product (the material certificates of the components that are in contact with the product are delivered with the machine)
  - Verification of calibration process instruments (the calibration certificates of the temperature probes supplied with the machine are delivered with the machine)
  - Verification of Installation and Software Version of the HMI and PLC
- I/O Verification
  - Start-up, shut down and communication failures
  - Screens verification
  - Access levels test (if required)
  - Verification of safety systems
  - Alarms and interlocks
  - Parameter management
  - Audit trail verification (if required)
  - Data backup and retrieval (if required)
  - Rejections
  - Operation test for each format
  - Dosing capacity/precision
  - Verification of report generation (if required)

	<b>DESIGN QUALIFICATION (DQ)</b>		<b>FAT_C004.01793</b>	
	<b>PH-28 DX- Customer Name</b>		Edition 03 abril 2023	Version 1.0


  


## FACTORY ACCEPTANCE TEST (FAT)

<b>Equipment:</b>	Horizontal Form Fill Seal Machine
<b>Type of equipment:</b>	PH-28 DX
<b>Serial Number</b>	#02204EF001
<b>Customer:</b>	Customer Name
<b>Document Reference:</b>	FAT_C004.01793
<b>Version:</b>	1.0
<b>Pages:</b>	212


  



 <small>A GLOBAL COMPANY</small>	<b>FACTORY ACCEPTANCE TEST (FAT)</b> <b>PH-28 DX- Customer Name</b>	<b>FAT_C004.01793</b>	
		<small>Edition</small> <b>03 April 2023</b>	<small>Version</small> <b>1.0</b>

TEST FAT - 04: MATERIAL CERTIFICATE VERIFICATION							
Table 1. Material Certificates (see Annex F of the User Manual)							
IL	Part No.	Components	Design material	Observed material		Result	Checked by <small>(initials&amp;date)</small>
				Material	Certificate No.		
Indirect contact							
1.	0FA00707000040010	COUNTERWEIGHT	AISI 316 L			<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> NA	
2.	0FA00107000090060	RUBBER STAMP	SILICONE 60ShA			<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> NA	
3.	0FA00507000150010	COMPENSATING ROLLER AXIS	AISI 316 L			<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> NA	
4.	0FA00707000040020	TAMPER SUPPORT SHAFT	AISI 316 L			<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> NA	
5.	0FA00107000090030	BUSHING	SILICONE 60ShA			<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> NA	

 <small>A GLOBAL COMPANY</small>	<b>FACTORY ACCEPTANCE TEST (FAT)</b> <b>PH-28 DX- Customer Name</b>	<b>FAT_C004.01793</b> <small>Edition</small> <b>02 April 2023</b> <small>Version</small> <b>1.0</b>
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**9.3.- TEST FAT - 01: DOCUMENTATION VERIFICATION**

Run No.:

**Objective**

Verify the availability of descriptive documentation, specifications, and manuals of the supplied and installed machine, and its components.

**Methodology**

All the descriptive documents, specifications, installation and configuration manuals and operation manuals, for the hardware, software and communication components of the system are listed in **Table 1**.

For each of the documents, enter the title, reference, version, and location.

Verify the documentation is:

- Clear and concise: It complies with documentation standards and it is easy to understand.
- Complete: non-ambiguous and well-defined information.
- Suitable for the purpose: should ensure that the system has the required attributes of reliability, maintainability, usefulness, and minimisation of risks.
- Current: the documentation exists in its latest version, and it is verified that the appropriate change control is applied.

**Acceptance criteria**

- 1- The documentation is available, clear, and consistent.
- 2- The documentation is complete.
- 3- The documentation is clearly identified and versioned.
- 4- The documentation is correctly archived.

# SAT (Site Acceptance Test) Protocol

**The purpose of the SAT protocol is to provide documentary evidence that the equipment has been delivered, installed and operates in compliance with its design specifications.**


**The following tests are included in the SAT protocol:**

- Document verification (Final version)
- Operation test for each format
- Dosing capacity/precision

**Each FAT and SAT test must include the following:**

- Purpose of the test;
- Methodology for test performance;
- Acceptance criteria: minimum parameter values required to accept the test;
- Comments section to describe failures deviations or enter observations;
- Checkbox for the signature of the person responsible for performing the test;
- Approval checkbox to be signed when the test is accepted.

When the verifications performed during the Pharma FAT and SAT tests are satisfactory, properly documented and not affected by machine transport or any changes made to the machine, they can be referenced in subsequent qualification stages without having to repeat the tests.

 <small>a vesella company</small>	<b>SITE ACCEPTANCE TEST (SAT)</b> <b>PH-28 DX- Customer Name</b>		<b>SAT_C004.01793</b>	
			<small>Edition</small> <b>03 abril 2023</b>	<small>Version</small> <b>1.0</b>

## SITE ACCEPTANCE TEST (FAT)

<b>Equipment:</b>	Horizontal Form Fill Seal Machine
<b>Type of equipment:</b>	PH-28 DX
<b>Serial Number</b>	#02204EF001
<b>Customer:</b>	Customer Name
<b>Document Reference:</b>	SAT_C004.01793
<b>Version:</b>	1.0
<b>Pages:</b>	212

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[illegible]



# IQ (Installation Qualification) Protocol

**The purpose of the IQ protocol is to verify that the machine has been installed according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. These checks are carried out without starting up the machine. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.**


**The following tests are included in the IQ protocol:**

- Preliminary verification (FAT Approval)
- Document verification (Final version)
- Conformity of the plans (Final version)
- Conformity of the components
- Verification of the parts in contact with the product (the material certificates of the components that are in contact with the product are delivered with the machine)
- Verification of calibration process instruments (the calibration certificates of the temperature probes supplied with the machine are delivered with the machine)
- Verification of Installation and Software Version of the HMI and PLC
- I/O Verification
- Verification of services (equipment supplies and connections)

 a coesia company	<b>INSTALLATION QUALIFICATION (IQ)</b>  <b>PH-28 DX- Customer Name</b>	<b><i>IQ_C004.01793</i></b>	
		<i>Edition</i> 03 abril 2023	<i>Version</i> 1.0

## INSTALLATION QUALIFICATION (IQ)

<b>Equipment:</b>	Horizontal Form Fill Seal Machine
<b>Type of equipment:</b>	PH-28 DX
<b>Serial Number</b>	#02204EF001
<b>Customer:</b>	Customer Name
<b>Document Reference:</b>	IQ_C004.01793
<b>Version:</b>	1.0
<b>Pages:</b>	180

 a cœula cœulante	INSTALLATION QUALIFICATION (IQ)  PH-28 DX – Customer Name	<b><i>IQ_C004.01793</i></b>	
		<i>Edition</i> 03 April 2023	<i>Version</i> 1.0

TEST IQ - 06: HARDWARE AND SOFTWARE VERIFICATION				
Table 3. HMI				
It.		Expected Results	Result	Checked by (initials&date)
Hardware	Identification	19A80	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	
	Brand / Manufacturer	IRONTECH	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	
	Model	IRTWPC158KCW7/A-2CDA	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	
	Logical Name	USUNXOSACHETF01	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	
	RAM	8GB	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	
	HDD	Partition C: 60 GB Partition D: 60 GB	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	
	Processor	Intel® Tiger Lake i5-1135G7	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA	

# OO (Operational Qualification) Protocol


**The purpose of this protocol is to verify that the machine operates according to the customer's requirements (URS) and/or the design parameters set out in the offer or order. The documentation includes an explanatory summary of each significant part of the machine and highlighting its function within the machine as a whole.**

**The following tests are included in the OQ protocol:**

- Preliminary verification
- Start-up, shut down and communication failures
- Screens verification
- Access levels test (if required)
- Verification of Safety Systems
- Alarms and interlocks
- Parameter Management
- Audit Trail Verification (if required)
- Data backup and retrieval (if required)
- Rejections
- Operation test for each format
- Dosing capacity/precision
- Verification of report generation (if required)

**Each IQ and OQ test must include the following:**

- Purpose of the test;
- Methodology for test performance;
- Acceptance criteria: minimum parameter values required to accept the test;
- Comments section to describe failures deviations or enter observations;
- Checkbox for the signature of the person responsible for performing the test;
- Approval checkbox to be signed when the test is accepted.

 <small>a united company</small>	<b>OPERATIONAL QUALIFICATION (OQ)</b> <b>PH-28 DX – Customer Name</b>		<b>OQ_C004.01793</b>	
			<small>Edição</small> <b>03 abril 2023</b>	<small>Version</small> <b>1.0</b>


  


## OPERATIONAL QUALIFICATION (OQ)

<b>Equipment:</b>	Horizontal Form Fill Seal Machine
<b>Type of equipment:</b>	PH-28 DX
<b>Serial Number</b>	#02204EF001
<b>Customer:</b>	Customer Name
<b>Document Reference:</b>	OQ_C004.01793
<b>Version:</b>	1.0
<b>Pages:</b>	200



  
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**PR2 08/01 – Operational Qualification ed. 01**

**PI**

	<b>OPERATIONAL QUALIFICATION (OQ)</b> <b>PH-28 DX- Customer Name</b>		<b>OO_C004.01793</b>	
			Edition 02 April 2023	Version 1.0

<b>TEST OQ - 16: OPERATIONAL TEST</b>					
<b>Table 4. Defective units (Format: F-1)</b>					
1.	Number of samples <sup>1</sup> :	200 pouches			
	<b>Type of Defect</b>	<b>AQL</b>	<b>Max. N° of defective units</b>	<b>Verifications</b>	<b>Result</b> (in bold & date)
	<b>Critical (C):</b> May cause a lack of sterility, container integrity or cause harm to patient: <ul style="list-style-type: none"> <li>Broken unit</li> <li>Pouches not dosed</li> <li>Leakages</li> <li>Data not printed</li> </ul>	0.1	0 units	Critical : ____ uts	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA
2.	<b>Major (M):</b> Defects that do not affect patient health or product functionality: <ul style="list-style-type: none"> <li>Damaged pouch (sealing not affected)</li> <li>Unclear print</li> <li>Damaged pouch (sealing not affected)</li> </ul>	1.5	≤ 7 units.	Critical : ____ uts	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA
	<b>Minor (Mn):</b> <ul style="list-style-type: none"> <li>Not very significant marks or scratches on the surface of the pouch</li> </ul>	2.5	≤ 10 units.	Critical : ____ uts	<input type="checkbox"/> P / <input type="checkbox"/> F / <input type="checkbox"/> NA

	<b>OPERATIONAL QUALIFICATION (OQ)</b> <b>PH-28 DX- Customer Name</b>		<b>OQ_004.01793</b>	
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<b>TEST OQ - 18: GxP REPORT GENERATION</b>		
Comments:		
Empty space for comments		
<b>TEST FINAL RESULTS</b>		
Result:	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL	
	<input type="checkbox"/> CONDITIONAL PASS	
Performed by:	Signature:	Date:
Reviewed by:	Signature:	Date:

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Volpak S.A.U  
Pol. Ind. Can Vinyalets  
C/ Can Vinyalets 4  
08130 Santa Perpètua de Mogoda  
Barcelona, Spain

[main@volpak.com](mailto:main@volpak.com)  
[www.enflex.es](http://www.enflex.es)

