

**ZS 高效筛粉机安装确认**  
**IQ**

版本: 2013-08-03

\*\*\*\*\*有限公司

2013 年 08 月

<b>Installation and Qualification Plan for ZS High-Efficiency Sieve Powder Machine</b>				
<b>Project</b>	<b>Department</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>Draft</b>				
<b>Review</b>				
<b>approval</b>				

Verify implementation time: \_\_\_\_\_ to \_\_\_\_\_

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**I、 Verify project name:**

Installation Qualification of ZS High-Efficiency Powder Sieving machine

**II、 Verification purpose:**

Through the installation qualification of ZS high-efficiency powder sieving machine, evaluate whether the system meets the requirements and operates normally, Check and confirm that the grinder is delivered as required by the contract, its installation complies with the design requirements, and the materials and documents meet the GMP regulations. Check and confirm that the equipment installation indicators meet the requirements. Document the confirmed requirements and acceptance criteria for equipment installation. Confirm and describe that the installation location of the equipment is correct and its purpose of use is clear. Prove that this is equipment is installed in accordance with the manufacturer's specification and technical requirements.

**III、 Team members and responsibilities**

Department	Name	Responsibilities
		Be responsible for drafting the validation scheme, summarizing and analyzing the data during the validation process, and preparing the validation report.。
		Be responsible for determining the equipment installation location and implementing and confirming other verification - related steps.
		Be responsible for determining the equipment installation location and implementing and confirming other verification - related steps.
		Review validation protocols and reports and supervise their implementation.

		Review validation protocols and reports and supervise their implementation.
		Review validation protocols and reports and supervise their implementation.

#### IV、 Verification content

##### 1. Equipment basic information

The ZS high-efficiency powder separator is mainly used to separate materials through different layers and different mesh sizes of sieves.

##### 2、 Technical documentation archiving

Objective: To confirm through documentation that the technical documents for the equipment and accessories have been archived.

Requirement: Based on the equipment configuration, create a comprehensive equipment information sheet and ensure that all relevant documentation related to the equipment has been properly archived as per regulations.

##### 3、 Index of engineering drawings related to equipment installation

Objective: To display the index of engineering drawings related to equipment and confirm that the relevant drawings have been archived as required.

Requirement: Review the wngineering drawings related to the equipment and register and drawings.

##### 4、 List of accessory equipment

Objective: To complete the list of auxiliary equipment based on the purchase order and technical specifications, confirming that all items have been installed according to the specifications.

Requirements: Based on the purchase order and technical specifications, complete the list of auxiliary equipment, indicating the installation location, equipment number, manufacturer, and technical parameters.

#### 5、Appliance Inspection Checklist

Objective: To verify that all electrical protection devices have been installed.

Requirements : Verify that all electrical protection devices have been installed according to the relevant standards.

#### 6、Apperance test

Objective: To check if the equipment's appearance has been damaged during production and transportation.。

Requirements: Inspect the equipment and all accessories on-site. The outer surfaces should have no obvious scratches or impact marks. All parts must be complete and undamaged, with no rust spots or corrosion. All connections should be intact.

#### 7. Material inspication of equipment components

Objective: To check if the material of critical components meets the process requirements.

Requirement: Check the material certificates of critical equipment to confirm that the material in contact with pharmaceuticals should be made of 304 stainless steel, and the gaskets should be made of silicone or PTFE.

#### 8. installation requirements

Objective: Inspect the installation of all components within the system to ensure that each part is installed according to specifications.

Ensure that the installation status of each component complies with relevant standards and requirements.

## 9.Public works

Objective: Inspect the utility connections of the equipment to ensure that the system's utilities meet process requirements and are installed according to specifications.

Requirements: The utility systems have been installed according to the process flow diagram.

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## 10 Safety measures

Project	Requirement	Test results
main unit	The main unit is properly grounded.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
main unit	The equipment was installed on-site smoothly and securely.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
leakage protection	The device can automatically cut off power in case of leakage.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Conclusion: <div style="text-align: center; opacity: 0.3; font-size: 48px; transform: rotate(-30deg); pointer-events: none;">Fangyuan Machinery</div>		
Inspector: _____ Date: _____		
Reviewer: _____ Date: _____		

## 11. Environment

Project	Requirements	Test results
Installation area	Class D control area	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Conclusion:		
Inspector: _____ Date: _____		
Reviewer: _____ Date: _____		

## 12. Verify the findings of the review team

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Reviewer's name: \_\_\_\_\_ Date: \_\_\_\_\_

## V、 Deviation handling

## VI、 Related attachments

## Attachment 1: Basic Information of ZS High-Efficiency Sieve Mill

Name	ZS High-Efficiency Sieve Separator	Device model	YK
Manufacturing date	2013 年 9 月	Equipment number	
Installation time	2013 年 9 月	Installation location	
Manufacturer	Jiangyin Fangyuan Machinery Co., Ltd.	Order number	
Nameplate data			
Main technical specifications of the equipment	capacity 50-400kg/h granularity 6-40 目 Main motor power 0.25kw noise ≤80dB(A)		
User Manual Title	ZS High-Efficiency Sieve Powder Machine Manual	Storage location	
Inspector:			Date:
Reviewer:			Date:

## Attachment 2: List of documents related to equipment

Number	Document name	Is data collection to be established	Whether to file	storage area
1	ZS High-Efficiency Sieve Packing List 单			
2	Equipment User Manual			
3	Certificate of Product Quality for Equipment			
6	List of spare parts			
7	Operator training records			
8	Completion drawings			
Conclusion:				
Inspector:			Date:	
Reviewer:			Date:	

## Attachment 3 Appliance checklist

## Attachment 3.1

electrical components	Supply voltage	Power supply phases	Total load	power panel	Switch specifications	Fuse specifications
Inspector:				Date:		
Reviewer:				Date:		

## Attachment 3.2 Motor connection status

Number	Electric motor name	model	series	voltage	electric current	power	rotational speed	Function	Category

## Attachment 4 Appearance Test

Number	Equipment Name	Project requirements	Test results
1	ZS High-Efficiency Powder Sieve and Its Accessories	The surface has no visible scratches or impact marks.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
		All parts are complete and undamaged (as per packing list)	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
		All sections and pipe connections are intact.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Conclusion:			
Inspector:		Date:	
Reviewer:		Date:	

## Attachment 5 Equipment Component Material Inspection Checklist

Number	Part name	Requirements	Inspection method	Result
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1	Sifting room main body	316L	Check the material certificate	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
2	Screen frame	316L	Check the material certificate	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
3	sieve	316L	Check the material certificate	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Conclusion:				
Inspector: _____ Date: _____				
Reviewer: _____ Date: _____				

## Attachment 6 Installation requirements checklist

Project	Requirements	Test results
Installation location	Consistent with the equipment layout plan	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Location of equipment placement	The platform should be installed on a solid and level surface.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	The equipment should be installed on a solid and level surface.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	The equipment should be properly installed and stable, with no swaying.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	The work environment must control dust concentration and prohibit open flames and static sparks.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Equipment	Ensure there is sufficient installation space and adequate	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

installation space	maintenance space.	
Installation method	Floor installation	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	All the sealing gaskets at the chuck connection points have been installed, and the chucks are securely tightened.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	All flange connections have been sealed with gaskets, and the bolts are securely tightened.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	The weld seam in contact with the material is smooth.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
	When connecting power, use explosion-proof cables and junction boxes.	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Conclusion:		
Inspector: _____ Date: _____		
Reviewer: _____ Date: _____		