

设计确认（方案）报告

项目名称：ZS 高效筛粉机

安装位置：*****

验证编号：V(D) R-DQ-J-设备编号

*****有限公司

2013 年 6 月

Report drafter	
File number	V(D)R-DQ-J-
Scope of application	适用于 ZS 高效筛粉机设计确认
Alternative version	----
Date	2013 年 6 月 日

Review of the verification report

(Authorized signature of the relevant authority)

I have reviewed and approved the design and validation report for the ZS High-Efficiency Powder Sieve.

Approver	Signature	department	position	Date
沈琴		质量保证部	主任	2013 年 6 月 日
陈强				
王军				

Approval of the validation report

(Signed by the members of the verification committee.)

Approve	Signature	department	position	Date
高崎	副总经理	总经理室	质量副总兼 QP	2013 年 6 月 日

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1、Verify the project name

Design confirmation plan for ZS high-efficiency flour sifting machine

2、Purpose of verification

Confirm the quality key points and basic requirements of the ZS high-efficiency powder screening equipment from user needs standards to functional standards. This includes verifying the technical specifications, parameters, and indicators of the selected equipment for their applicability, examining whether they meet the production process requirements, relevant regulatory requirements, calibration, maintenance, cleaning, and sterilization requirements. The assessment covers hardware, software, and comprehensive evaluation to ensure that the equipment specifications comply with those specified in the contract and to supervise the corresponding services provided by the supplier according to the contract.

3、Personnel and responsibilities of the verification team

Department	Name	Responsibilities
Extraction workshop		Responsible for drafting validation protocols, consolidating and analyzing data during the validation process, and writing validation reports.
Power equipment		Responsible for implementing and confirming equipment design parameters and other validation-related steps.
Quality Assurance Department		Responsible for implementing and confirming equipment design parameters and other validation-related steps.
Chief Engineer		Review verification plans and reports, and oversee their

		implementation.
Production and Manufacturing Department		Review verification plans and reports, and oversee their implementation.
Qualified Person for Quality		Review verification plans and reports, and oversee their implementation.

4、 Cited Standards

This document confirms that it refers to and cites the following relevant standards.

4.1 Good Manufacturing Practice for Pharmaceutical Products, 2010 Edition;

4.2 Pharmacopoeia of the People's Republic of China, 2010 Edition;

4.3 GB-52261-2008 Mechanical Safety (Mechanical Electrical Equipment Part 1: General Technical Conditions)

4.6 The standard for pharmaceutical engineering equipment OSAHS18001 issued by the China Pharmaceutical Equipment Association;

5、 Design verification and validation content

5. 1、 ZS High-Efficiency Powder Screening Machine Performance Parameters Setup

Project	Requirements standards	Does it meet the requirements?
capacity	50-400kg/h	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Screen mesh size	60-120 mesh	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Main motor power	0.25kw	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Noise	≤80dB(A)	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

5.2 ZS High-Efficiency Sieve Separator Structure Types and Dimension Settings

Project	Requirements standards	Does it meet the requirements?
ZS High-Efficiency Sieve Separator Overall	upright	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Feed inlet height	约 1145mm	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Outlet height	约 770mm	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

5.4 The main materials of the ZS high-efficiency flour sifter

Project	Requirements standards	Does it meet the requirements?
Sifting room	316L	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Screen frame	316L	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
screen mesh	316L	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
clamping band	304	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
base	carbon steel	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
outsourced board	304	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
electric motor	0.25KW	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

5.5 Primary wall thickness of the equipment

Project	Requirements standards	Does it meet the requirements?
Cover	1.5 mm	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
flour sieving room	1.5 mm	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
base	3 mm	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

5. 6 Surface roughness setting for the equipment

Project	Requirements standards	Does it meet the requirements?
Inner surface of the equipment	Sub - mirror mechanical polishing $Ra \leq 0.8\mu m$	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
External surface of the equipment	Satin finish mechanical polishing $Ra \leq 1.6\mu m$	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
Inner surface of the equipment	No angles and grooves	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>
External surface of the equipment	No sharp edges and burrs	Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

6、 Checklist for outstanding items in design confirmation

Checklist for outstanding items in design confirmation				
Number	Outstanding items	Handling measures	Inspector	Note

7、 Design confirmation deviation form

Design confirmation deviation form				
Number	Outstanding items	Handling measures	Inspector	Note

8、 Design Confirmation Summary Report

Design Confirmation Summary Report

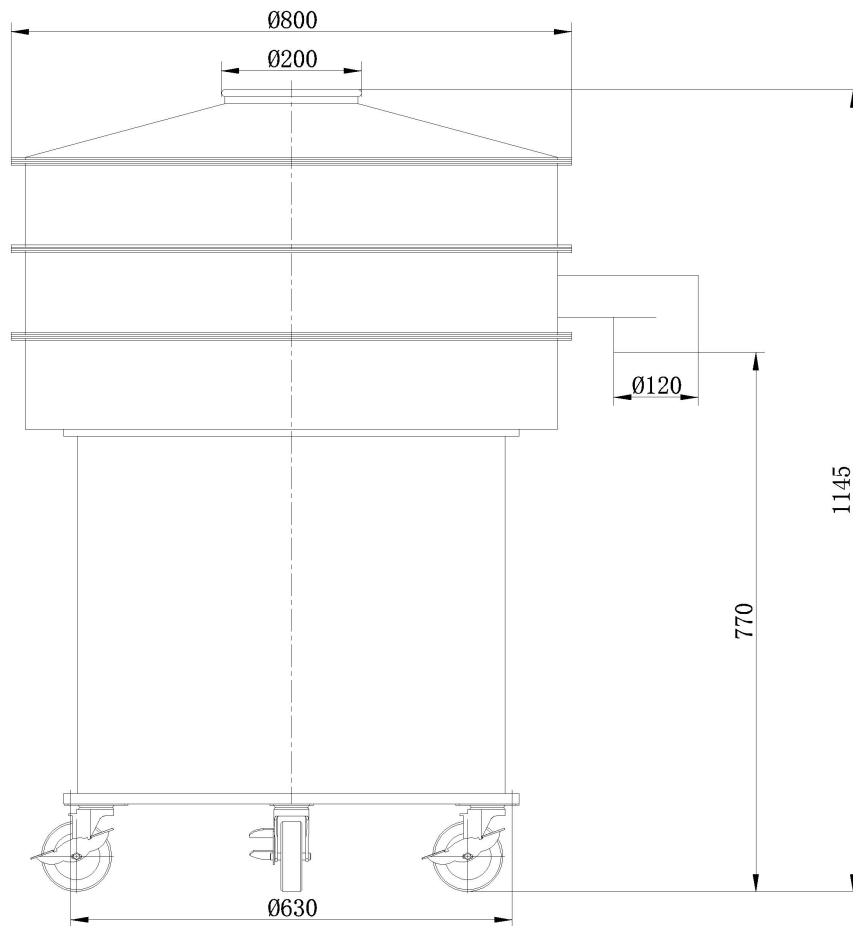


Inspector: _____

Reviewer: _____

9、Attachment

9.1 High-efficiency ZS flour sifting equipment diagram



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