Validation Guide

LeDetic® Single-use Powder Feeding Bag

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1. Overview

Single-use systems are widely used in the operation of biopharmaceutical processes, involving the manufacturing processes of antibodies, vaccines, recombinant proteins, cell and gene therapy, nucleic acid drugs, etc. The application scope of common single-use systems in pharmaceutical processes includes cell culture, buffer, media, intermediates, drug substance, final drug product, sampling, etc. With the rapid development of the biopharmaceutical industry, it has also boosted the demand for quality consistency, supply assurance, business continuity and change management of single-use products.

The brand-new LeDetic™ film (code: D) developed by Shanghai LePure Biotech Co., Ltd. ("LePure Biotech") and the corresponding single-use process film bag can be used for powder transfer, weighing, feeding, etc.

LeDetic™ film was developed independently by LePure Biotech and is a Static dissipative grade material suitable for powder feeding. Advanced multilayer co-extrusion technology is used in the manufacture of the film material. The new raw material provides the film with high-quality and stable physical properties and biological safety.

1.1. Manufacturing Site

The LeDetic™ film is manufactured in a Grade D cleanroom with real-time continuous dynamic environmental monitoring. The test data indicate that the air environment (number of dust particles and passive airborne viable) in contact with the film around the co-extruded-film equipment can meet the dynamic Grade C criteria.

The basic information of the manufacturing site of single-use powder feeding bag made of LeDetic™ film are as follows:

The total area of the Lingang Factory is 10,078 m^2, including the Grade D clean area of 450 m^2, the Grade C clean area of 3,400 m^2, and the Grade C + A clean area of 600 m^2.

2. Quality Assurance

2.1. Quality Management System

The current quality systems of all manufacturing sites of LePure Biotech are in compliance with ISO 9001 standards. At the same time, the quality system has been upgraded in accordance with the requirements of ISO 13485 to further meet the needs of biopharmaceutical enterprises.

2.2. Manufacturing Management

The production of single-use systems of LePure Biotech is performed in the ISO 7 clean room, and the critical production steps are carried out in the ISO 5 clean area.

Both the production equipment and instruments have passed 3Q validation, and they cannot be put into production until their calibration is completed. The production equipment is kept in a good condition through regular maintenance.

Production plans are managed through a unified internal process, and orders, drawings, customer requirements, production schedules, etc. are confirmed by relevant personnel.

The production materials are inspected before warehousing and they cannot be released for the production of single-use products only after meeting the requirements.

During the production of single-use products, quality management personnel or designated personnel shall perform real-time testing and qualification of the production process and materials, including but not limited to: consistency with technical drawings, material inspection, visual inspection (cleanliness of components, sealing, foreign matter,

firmness, assembly, etc.), dimensional inspection, packaging, labeling, etc.
Corresponding batch production records should be kept for each batch of semi-finished products and finished products, so that the production history and quality related status of that batch can be traced.

2.3. Material Control and Supplier Management

According to the characteristics of the single-use system, the selection criteria, management methods and audit specifications for suppliers have been established. The quality of raw materials and components used is strictly controlled. Raw materials and components used for production are controlled according to risk grades. Typical raw materials and components should meet the following basic requirements:

- Conform to USP <87> and USP <88> Class VI, and/or ISO 10993
- TSE/BSE-free
- USP 661 compliance
- USP <85> Endotoxin
- USP <788> Particulate Matter Testing
- USP <790> Visible Particulates
- Conform to other regulatory compliance documents

All raw materials and components, including supplier's quality documents, packaging and labeling, need to be confirmed by in-house QC testing, spot check by infrared spectroscopy (FTIR), appearance inspection, dimensional inspection, etc.
Regular supplier audits are conducted to review the quality of raw materials and components to ensure consistency and reliability.

2.4. Personnel

LePure Biotech has a number of production, quality, and management personnel and technicians with corresponding expertise in the single-use system, and all meet the relevant personnel qualification requirements specified in ISO 9001 Requirements of Quality Management System. Ongoing personnel training and qualification assessment are performed to ensure that employees have a clear understanding of the required criteria. Employee qualifications are measured through strict initial screening and continuous competency testing.

2.5. Change Management

Based on a scientific and risk-based approach, LePure Biotech has fully assessed the factors affecting the performance of the manufacturing process and the quality of the final product, and established a systematic change management strategy.
In case of situations that affect the consistency and quality reliability of the product, such as changes in film recipe or important manufacturing process parameters, LePure Biotech will generally notify the user at least 1 year in advance to ensure that the user has sufficient time to perform relevant assessment.

2.6. Gamma Sterilization Process

The VDmax validation method using the minimum sterilization dose (e.g., 25 kGy or 40 kGy) and the method for validating the sterilization cycle are used, as specified in ISO11137 Part 1&2:2013. A representative product family is selected to determine the average microbial load and carry out the experiment. The gamma irradiation dose range of 25-40 kGy is finally selected and confirmed to be able to achieve the sterility assurance level SAL = 10^{-6}.

3. Physical Property Testing of LeDetic™ Film

LeDetic™ film is developed specifically for biopharmaceutical processes. In order to adequately ensure good performance, the best and optimal particle ratio was finally adopted in the selection of LeDetic™ particles through multiple formulation and extrusion experiments. The physical properties of the film have been improved by optimizing the film recipe to improve its tensile strength, heat seal strength, puncture resistance, anti-twisting and anti-static properties, and low adsorption.

3.1. Film Structure

The film is measured in a calibrated digital instrument, film thickness: 220 μm ± 20 μm.
The outer layer and the innermost layer are made of linear low-density polyethylene (LLDPE), which can resist the damage caused by external puncture, rubbing, tear and twisting;
The middle layer is made of low-density polyethylene (LDPE), which provides good support for the film and the bag;

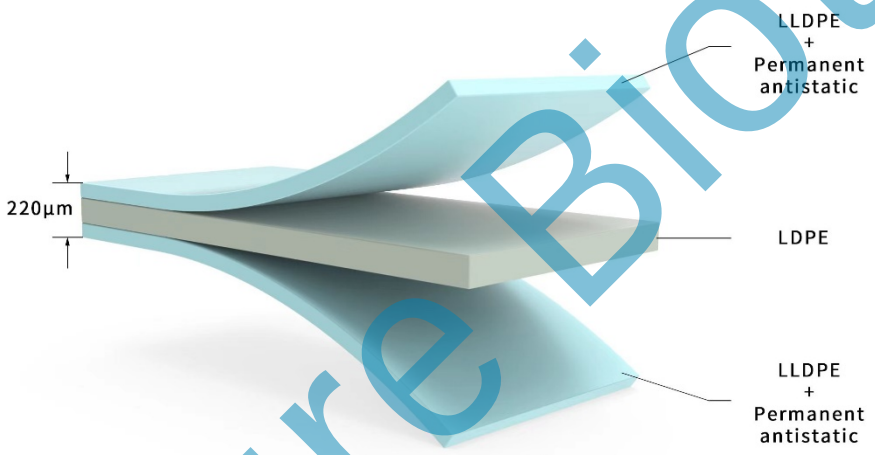

Figure 1. Structure of LeDetic™ Film

3.2. Film Parameters

The following data are the physical parameters of the LeDetic™ film, which constitute the basis of the film properties.

Table 1. LeDetic™ Film Parameters

Test Item	Test Method	Before Irradiation	After Irradiation
Film thickness (μm)	ASTM-D6988	225	225
Tensile strength, MD (Mpa)	ASTM-882	32	31

Tensile strength, TD (Mpa)		29	27
Elongation at break, MD (%)		760	750
Elongation at break, TD (%)		720	740
Intensity of puncture (N)	ASTM-F1306	35	37
Dart impact (g)	ASTM-D1709	1700	1500
Anti-twisting property (number of micropores)	ASTM-F392	0	0
Surface resistivity (Inner)	ASTM-D257	10^{10}	10^{10}
Surface resistivity (Outer)		10^{10}	10^{10}

3.3. Physical Strength

According to ASTM E3051-16, some strength indicators of the film were tested, including:

- Tensile strength at break
- Anti-puncture
- Anti-twisting
- Impact resistance
- Heat seal strength

Three different batches of film samples were used for each performance test to compare the performance indicators before and after irradiation. Irradiation was performed in accordance with ISO 11137 with an irradiation dose of 45-55 kGy.

3.3.1. Tensile Strength at Break by ASTM D882

Tensile testing is a test of the stress produced by the film under different strains (stretch deformation length). The purpose of this test is to determine the counter force produced by the film when it is stretched with an external force and the energy required when the film is stretched and broken.

3.3.1.1. Test Methods

This test is performed according to ASTM D882 standard. A 15 mm-wide film is fixed on a tensile tester by an upper mechanical clamp and a lower mechanical clamp with a distance of 50 mm, and then the film is stretched at a constant rate of 500 mm/min until it breaks.

In this test, the elastic modulus represents the proportional relationship between stress and strain (Hooke's law) during the elastic deformation stage of the film, and the proportional coefficient is the elastic modulus. Elastic modulus is a physical quantity describing the ability of the material to resist deformation, and the greater numerical value indicates the higher film rigidity; conversely, it indicates the higher ductility of the film (Figure 2). Elongation at break represents the strain of the film when it breaks in tension, usually expressed as a percentage. The breaking strength represents the stress strength of the film when it breaks in tension, usually in MPa or N (Figure 2).

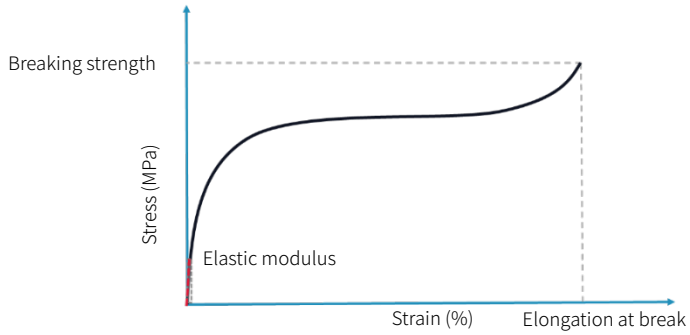

Figure 2. Tensile Curve of Sample Film Stripe

In the process of film processing and molding, the film winding direction is the MD-Machine Direction, also called the Longitudinal Direction; while the TD-Transverse Direction is perpendicular to the MD-Machine Direction, also called the Transverse Direction (Figure 3).

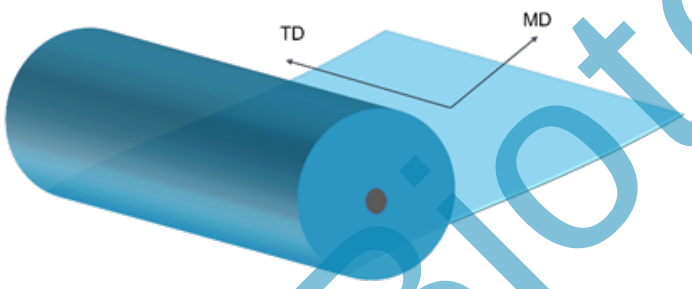

Figure 3. Schematic Diagram of Film's MD and TD

3.3.1.2. Test Results

Table 2. Test Results of Tensile Strength of LeDetic™ Film at Break

Standard	Test	Unit	Direction	Test Value (Before irradiation)	Test Value (After irradiation)
ASTM D882	Elongation at break	%	MD	760	750
			TD	720	740

3.3.2. Anti-puncture Property by ASTM F1306

The anti-puncture test is performed by applying an external force to the film at a certain speed with a probe in the direction perpendicular to the film until the film is perforated (Figure 4). This test predicts the risk of single-use bags being punctured by sharp objects during packaging, shipping, or use.

3.3.2.1. Test Methods

This test is performed according to ASTM F1306 standard. A conical needle is used in the test and the maximum puncture force and puncture distance during the test are recorded. The maximum puncture force represents the maximum stress produced when the film is strained during the application of an external force to the film by a probe until the film is perforated, usually in N. The maximum puncture distance represents the strain length of the film at the time of being perforated by a probe, usually in mm.

The test probe is tapered, with a needle diameter of approximately 3.2 mm, and the film is a circular sample with a diameter of 35 mm and is fixed by clamps. The probe gradually penetrates the film at a rate of 25 mm/min at a position perpendicular to the central point of the film.

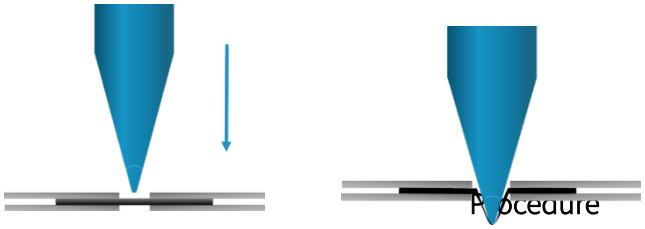

Figure 4. Puncture Test Procedure

3.3.2.2. Test Results

Table 3. Test Results of Anti-puncture of LeDetic™ Film

Standard	Test	Unit	Test Value (Before irradiation)	Test Value (After irradiation)
ASTM F1306	Maximum puncture force	N	35	37

3.3.3. Anti-twisting Property by ASTM F392 B

The anti-twisting test detects whether the film is still able to maintain integrity after repeated twisting and extrusion in a spatial dimension. This test can evaluate the resistance of the film against twisting and bending damage during production, processing, shipping, use, etc.

3.3.3.1. Test Methods

The test is performed in accordance with the ASTM F392 B standard with a torque of 15 cm and a torsion angle of 440° in the vertical direction for a total of 900 twists (Figure 5). At the end of the test, the number of micropores is determined by ink penetration method, and the smaller number represents the better anti-twisting property.

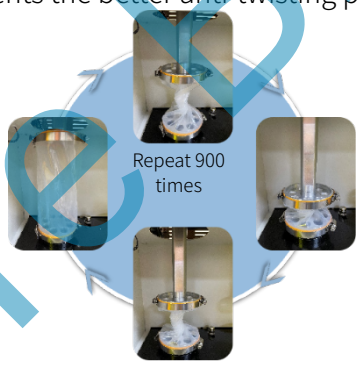

Figure 5. Anti-twisting Test

3.3.3.2. Test Results

Table 4. Test Results of Anti-twisting of LeDetic™ Film

Standard	Test	Unit	Test Value (Before irradiation)	Test Value (After irradiation)
ASTM F392 B	Anti-twisting: number of pinholes produced after 900 times of twists	Number per piece of film	0	0

3.3.4. Impact Resistance by ASTM D1709

The impact resistance is one of the important indicators of the film. The intensity of the impact strength of the film directly affects the ability of the film to withstand external impact, indicating whether the single-use bag can maintain its integrity when impacted.

3.3.4.1. Test Methods

This test is performed according to ASTM D1709 standard using Method A. The diameter of the test sample is 150 mm. The weight falls freely from a fixed height of 660 mm, if the film is not broken, increase the weight of the weights, and conversely, if the film is broken, reduce the weight of the weights. Repeat the test for no less than 20 times and calculate the impact strength when the breakage rate is right 50%.
Impact strength indicates the impact force of the film at 50% breakage, usually in g.

3.3.4.2. Test Results

Table 5. Test Results of Impact Resistance of LeDetic™ Film

Standard	Test	Unit	Test Value (Before irradiation)	Test Value (After irradiation)
ASTM D1709	Impact strength	g	1700	1500

3.3.5. Heat Seal Strength by ASTM F88

The heat seal strength has the most direct effect on the integrity of the single-use bag. Reasonable heat sealing process parameters have been validated to ensure the stability of the bag body welding process.

3.3.5.1. Test Methods

Two pieces of 15-mm wide films were heat-sealed according to ASTM F88. After complete cooling (at least 24 h), the two films were stretched in opposite directions with a tensile tester until peel or breakage at the heat seal. In this process, the maximum stress tested by the tensile machine is the heat seal strength, usually in N/cm or N/15 mm.

3.3.5.2. Test Results

Table 6. Test Results of Heat Seal Strength of LeDetic™ Film

Equipment Used	Drum Pulse Welder				Process Description	Drum Welding				
Category	Heating temperature (°C)	Welding time (min)	Pressure (N)	Cooling temperature (°C)	Cooling time (min)	S. No	Heat sealing strength N/15 mm			Test results
Upper Limit	168	30	0.25	95	5	1	30.201	33.128	34.811	Accepted
						2	33.528	33.28	34.992	Accepted
						3	30.677	33.315	34.073	Accepted
Median	165	30	0.25	95	5	1	27.928	25.589	25.032	Accepted
						2	27.812	29.133	25.709	Accepted
						3	29.483	28.58	26.354	Accepted
Lower Limit	162	30	0.25	95	5	1	20.128	23.244	24.961	Accepted
						2	22.906	24.316	23.518	Accepted
						3	22.03	21.287	21.77	Accepted
Equipment Used	Open Feeding Port Welder				Process Description	Cone Welding				
Category	Heating temperature (°C)	Welding time (min)	Pressure (N)	Cooling temperature (°C)	Cooling time (min)	S. No	Overlapping breaking force N/15 mm			Test results
Upper Limit	146	25	0.3	NA	NA	1	44.323	38.308	48.181	Accepted
						2	44.955	48.803	38.349	Accepted
						3	51.005	48.834	50.046	Accepted
Median	143	25	0.3	NA	NA	1	47.334	52.78	40.898	Accepted

						2	50.444	37.325	43.054	Accepted
						3	41.839	41.285	46.372	Accepted
Lower Limit	140	25	0.3	NA	NA	1	37.062	39.534	38.452	Accepted
						2	34.842	40.146	47.942	Accepted
						3	33.801	49.867	52.878	Accepted
Equipment Used	18# Pulse Sealing Welding Machine				Process Description	Cone Sealing				
Category	Heating temperature (°C)	Welding time (min)	Pressure (N)	Cooling temperature (°C)	Cooling time (min)	S. No	Heat sealing strength N/15 mm			Test results
Upper Limit	143	15	0.25	80	5	1	29.42	31.281	28.794	Accepted
						2	29.698	31.69	31.068	Accepted
						3	28.512	30.875	31.331	Accepted
Median	140	15	0.25	80	5	1	24.755	33.187	34.18	Accepted
						2	23.784	27.85	33.622	Accepted
						3	24.108	24.335	24.669	Accepted
Lower Limit	137	15	0.25	80	5	1	29.368	25.327	23.258	Accepted
						2	25.302	27.498	26.266	Accepted
						3	27.315	28.035	23.27	Accepted

3.4. Surface Resistivity by ASTM D257

Surface resistivity is an important data to characterize anti-static properties, which reflects the resistance value between two electrodes per unit square area. According to IEC industry regulations, the static dissipative material is defined as a material with a surface resistivity of 10^5 - 10^{11}. Standard: ASTM D257. The test results are shown in the following table:

Table 7. Surface Resistivity Test Results

Standard	Test	Unit	Test Value (Before irradiation)	Test Value (After irradiation)
ASTM-D257	Surface resistivity (Inner)	Ω/m^2	10^9	10^9
	Surface resistivity (Outer)		10^9	10^9

3.5. Powder Adsorption Rate Test

The powder bag made of the film is suitable for filling the powder for feeding operations, and the adsorption rate of the film and the recovery rate of the bag body are particularly important.

In order to simulate the customer's use scenario, 3 kg each of medium powder, diatomaceous earth and other powder were selected and filled into 25 L tapered powder bags made of the film. The weights before filling, after filling and after pouring were recorded, respectively, and the adsorption rates of the bags for different powders were calculated.

Calculation formula: the mass of the empty bag before filling was recorded as A, the mass of the full bag after filling was recorded as B, and the mass after pouring was recorded as C

Powder fill D = B - A Powder residue E = C - A

Adsorption rate = 100% × ((D - A) ÷ D)

Collection rate = 1 - Adsorption rate

Table 8. Test Results of Powder Adsorption Rate

Powder Name	Before Irradiation	After Irradiation
Medium powder 25 L	99.90%	99.90%
Diatomaceous earth 25 L	99.91%	99.91%
Lactose hydrate 25 L	99.92%	99.91%
Flour 25 L	99.91%	99.91%
Sodium bicarbonate 25 L	99.93%	99.93%

The test results showed that the adsorption rate of the powder feeding bag made of LeDetic™ film is extremely low.

3.6. Biocompatibility Test

The biocompatibility test of LeDetic™ film was performed after gamma irradiation (45-50 kGy). At the same time, the film after accelerated aging for 3 years was also tested.

Table 9. Biocompatibility Test Results

Regulatory References	Item	Result
USP<661>	Physicochemical Tests for Plastics	Pass
USP<85>	Endotoxin	Pass
USP<788>	Particulate Matter Testing	Pass
USP<790>	Visible Particulates	Pass
REACH Certification	REACH Certification	Pass
ROHS Certification	ROHS Certification	Pass
USP <87>	In vitro biological response	Pass
USP <88> Class VI	In vivo biological response	Pass

3.7. Film Aging Test

Table 10. Film Aging Test Results (Before Irradiation)

Test Item	Test Method	1 year	2 years	3 years
Film thickness (μm)	ASTM-D6988	225	225	225
Tensile strength, MD (Mpa)	ASTM-882	30	33	34
Tensile strength, TD (Mpa)		27	26	27
Elongation at break, MD (%)		769	731	768
Elongation at break, TD (%)		737	712	747
Intensity of puncture (N)	ASTM-F1306	31	34	33
Dart impact (g)	ASTM-D1709	1500	1570	1520
Anti-twisting property (number of micropores)	ASTM-F392	0	0	0
Surface resistivity (Inner)	ASTM-D257	10^{10}	10^{10}	10^{10}
Surface resistivity (Outer)		10^{10}	10^{10}	10^{10}

Table 11. Film Aging Test Results (After Irradiation)

Test Item	Test Method	1 year	2 years	3 years
Film thickness (μm)	ASTM-D6988	225	225	225
Tensile strength, MD (Mpa)	ASTM-882	34	30	33

Tensile strength, TD (Mpa)		28	24	28
Elongation at break, MD (%)		783	733	795
Elongation at break, TD (%)		759	700	769
Intensity of puncture (N)	ASTM-F1306	35	34	32
Dart impact (g)	ASTM-D1709	1450	1480	1360
Anti-twisting property (number of micropores)	ASTM-F392	0	0	0
Surface resistivity (Inner)	ASTM-D257	10^{10}	10^{10}	10^{10}
Surface resistivity (Outer)		10^{10}	10^{10}	10^{10}

4. LeDetic™ Single-Use Powder Feeding Bag

4.1. Application and Operation Unit

- Mounted on a loading bracket with a fixed size
- Used for powder transfer, weighing and feeding in biopharmaceutical process applications

4.2. Working Volume

Volume / Description	500mL	1L	5L	10L	25L	50L
Working volume (L)	500mL	1L	5L	10L	25L	50L
Maximum working volume (L)	550ml	1.1L	5.5L	10.1L	27.5L	50.5L

5. LeDetic™ Single-Use Powder Feeding Bag Test

LeDetic™ film and bag body have been tested for tensile strength at break, anti-puncture, anti-twisting, impact resistance, heat seal strength, surface resistivity, powder adsorption and biocompatibility. Tests for working volume, suspension and load bearing of LeDetic™ single-use powder feeding bag have also been completed, and the bag can provide reliable and safe performance for users in the biopharmaceutical process.

Depending on the nature of the validation method, each component, representative test bag or final product containing all relevant components were validated.

5.1. Suspension Test

Table 12. Suspension Test Results

S. No	Product Volume	Amount of Powder (Water) Filled/L (Kg)	Duration of Suspension	Test Results
1	5L	10L	24h	Accepted
2	10L	13L	24h	Accepted
3	25L	33L	72h	Accepted
4	5L	4.2kg	24h	Accepted
5	10L	8.3kg	24h	Accepted
6	25L	22.9kg	24h	Accepted
7	5L	8L	24h	Accepted
8	10L	13L	24h	Accepted
9	25L	30L	24h	Accepted

5.2. Drop Test

Table 13. Drop Test Results

S. No	Product Volume	Amount of Powder (Water) Filled/L (Kg)	Drop Height/mm	Drop Test Conclusion
1	5L	5	760	Accepted
2	10L	10	610	Accepted
3	25L	25	460	Accepted
4	5L	5	760	Accepted
5	10L	10	610	Accepted
6	25L	25	460	Accepted
7	5L	5	760	Accepted
8	10L	10	610	Accepted
9	25L	25	460	Accepted

Attachment: Reference Rationale for Drop Test

Weight of Packaged Products				Drop Height		Impact Speed	
⩾		<		Free fall		Slope or level	
lb	Kg	lb	Kg	inch	mm	ft/sec	m/sec
0	0	21	10	30	760	13	3.9
21	10	41	19	24	610	11	3.5
41	19	61	28	18	460	10	3
61	28	100	45	12	310	8	2.5
100	45	150	68	8	200	6.6	2

5.3. Integrity of LeDetic™ Single-Use Powder Feeding Bag

5.3.1. Integrity of Bag Body and Assemblies

The manufacturing process has been validated, and the raw materials, manufacturing processes and final products have been monitored and controlled accordingly.

Item	Test	Reference Method/Standard	Result
Welding firmness	Whether there are insufficient welding, missing welding, or wrinkles	100% visual inspection and in-house acceptance criteria	Accepted
Clamp/strip firmness	Whether the welding and connection positions are correct	100% visual inspection and in-house acceptance criteria	Accepted
Package integrity	The integrity of the vacuumed packaging to confirm whether the secondary packaging was complete	100% visual inspection	Accepted

5.3.2. Product Release and Manufacturing Control

Control of raw materials, manufacturing processes, and finished products has been established for the manufacturing of LeDetic™ film and LeDetic™ single-use powder feeding bag made of the film.

For control of raw materials

Item	Reference Standard	Acceptance Criteria as Defined by Regulations	In-house Release Criteria of LePure Biotech
Appearance, size	In-house method	/	In-house accepted size
Material identification	FTIR	/	Conformance with FTIR spectrum
Endotoxin	USP<85>, CHP<1143>	＜0.25 EM/mL	＜ 0.125 EM/mL
Visible Particulates	Visual inspection, in-house method	/	⩽ 3 particles/50 mL

For in-process control

Item	Reference Standard	In-house Release Criteria of LePure Biotech
Appearance, size	In-house method	In-house accepted size
Heat seal strength	ASTM F88	⩾20 N / 15 mm
Conformance of product manufacturing with the drawing	Drawing	100% product complies with the drawing
Manufacturing flow	in-house procedure	100% meets manufacturing requirements

For final product testing

Item	Reference Standard	Acceptance Criteria as Defined by Regulations	In-house Release Criteria of LePure Biotech
Heat seal strength	ASTM F88	/	⩾20 N / 15 mm
Connection firmness	In-house method	/	In-house accepted size
Endotoxin	USP<85>, CHP<1143>	＜0.25 EM/mL	＜0.125 EM/mL
Visible Particulates	Visual inspection, in-house method	/	⩽ 3 particles/50 mL

Sterility assurance

The loading form and dose of irradiation have been validated according to the acceptance criteria specified in ISO11137 for VDmax[25]. The range of irradiation dose used in actual manufacturing is 25-40 kGy and the sterility assurance level SAL = 10^{-6}. At the same time, representative products will undergo bioburden testing and dose review every 3 months, and each batch of products will be provided with an irradiation certification to confirm that the irradiation dose meets the validation requirements.

5.4. Physicochemical Tests of LeDetic™ Single-Use Powder Feeding Bag

5.5.

5.4.1. USP <661>: Containers, Physicochemical Tests - Plastics

The bag was irradiated with 45-55 KGy gamma rays prior to the test to assess compliance with USP <661> criteria after irradiation sterilization.

Test Method	Test Item	Judgment Criteria	Result
USP<661>	Buffer performance	⩽10.0 mL	Accepted
	Heavy metals	⩽1 ppm	Accepted
	Non-volatile residues	⩽15 mg	Accepted
	Residue on ignition	⩽5 mg	Accepted

5.6. Compliance with Other Regulatory Guidelines

LeDetic™ single-use powder feeding bags comply with the latest regulations and there is no BSE/TSE source in the raw materials and manufacturing process of the film.

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