Shanghai Jia Tian Pharmaceutical Packaging Co.,Ltd.

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Shanghai Jia Tian Pharmaceutical Packaging Co.,Ltd.

—High Quality Tube & Cans

www.jiatiantube.com

Canister for pMDI

Company Profile

Shanghai Jia Tian Pharmaceutical Packaging Co., Ltd. was established in 1990. We are a leading producer of aluminum pharmaceutical packaging. Our product range includes: Aluminum pMDI canisters (plain, FEP-coated),Aluminum aerosol cans and Aluminum collapsible tubes.

Located in No.3058 TingFeng Rd, Zhujing Town, Jinshan District ,Shanghai, China, covering an area of 50,000 square meters and employing over 350 staff. We operate nine automated high-speed production lines imported from abroad: Five lines specialize in aluminum collapsible tubes, with an annual capacity of 250 million units .Four lines specialize in aluminum cans, with an annual capacity of 200 million units.

As a member of the China Pharmaceutical Packaging Association (CNPPA), we hold CDMF, FDA, ISO 15378, and ISO 9001 certifications. For decades, we have adhered to our "quality first" strategy, focusing on high-quality aluminum packaging for pharmaceutical customers. Our products have earned strong recognition from clients worldwide.

Awards and Honors

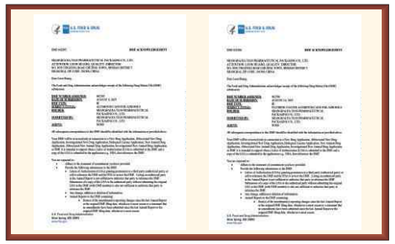
FDA Certification

FDA Test Report 1

FDA Test Report 2

ISO 15378

ISO 9001:2015



IFDA Certificate

Registration Number	Production name	Business Address	Product source	Specification	Update time	The association status with the formulation	Note
B20190008600	Aluminum medicinal ointment tube	Tingfeng Road, Zhujing Town, Jinshan District, Shanghai	China	/	/	A	National Pharmaceutical Package Mark 20120498
B20190007686	Medicinal aluminum aerosol can			ϕ20mm, ϕ25mm	/	A	National Pharmaceutical Package Mark 20160079
B20190007649	Solid medicinal aluminum cans			/	/	A	National Pharmaceutical Package Mark 20160219
B20250000521	Aluminum can for aerosols			5-25ml	20250729	/	/
B20250000522	Fluorine-coated aluminum can for aerosols			5-25ml	20250729	/	/

CDE register number

Company History

1990 Jia tian was established in 1990, imported 1st aluminum tube line from Germany and being supplier of Bristol–Myers Squibb Company

1992 Imported 2nd aluminum tube line from Germany and being aluminum tube supplier of Xian Janssen Pharmaceutical Ltd

1997 Imported 3rd production line from Germany for GSK, Schering-Plough, Novartis, Bayer

2000 Chinese government began to conduct GMP certificate, Jiatian is one of the first company to be approved and meanwhile we imported 1st aerosol can production line supplying to Yunnanbaiyao and Roche Pharmaceutical

2003 New company began to build and we imported 4th production line becoming draftsman of aluminum tube industrial standard for YY0249-2004

2005 New company completed, production transferred to new area and passed SFDA audit

2006 Registered in US FDA and began to supply for GSK Korea, Bayer Indonesia, Bayer Australia, Jamjoom Pharma (Saudi Arabia) and so on

2007 Began to supply L'Oreal (China, Korea, Japan, India), Henkel (China), Hoyu (China, Japan), Napla(Japan), Revlon (US) and so on

2009 Purchasing 2 aluminum tube lines from Germany and replaced one old line

2010 Being draftsman of Chinese aerosol can industrial standard for GB/T25164-2010, achiveing Breeding Award for Shanghai Little Giant Project

2012 Purchasing one aerosol can production line from Germany company of Hinterkopf and M+H

2014 Supplying Coca-Cola (Brazil, Japan, UK, USA, Italy, France and other 20 countries in total) 2014 FIFA world cup aluminum cans (Brazil)

2016 Purchasing one aerosol can line from Germany and one tube line from PSG (to replace one old tube line) by investing RMB 93 millions.

2017 Introducing system docking of logistics information management system WMS and company current ERP, we can provide superior service to our customers, speeding up from order placement to delivery, we also set up full automatic stereoscopic warehouse to increase our warehousing capacity.

2019 The new automatic high-speed aerosol line was installed and debugge (to replace an old aerosol line) .Start to develop PMDI cans.

2022 The 4th new automatic high-speed aerosol can production line and 1st inhalation aerosol can production line were installed and validated in the year of 2022.

Customers

Some customers

BAYER HealthCare

Jewim Pharmaceutical (shandong) CO. , LTD

Qilu Pharmaceutical Co.,Ltd.

Sandoz(China)Pharmaceutical Co.,Ltd.

YUNNAN BAIYAO GROUP CO.,LTD

Novartis China

GlaxoSmithKline Tianjing Company

Xian Janssen Pharmaceutical Ltd.

Johnson & Johnson China Ltd.

Jiangsu Hengrui Medicine Co.,Ltd.

KEEPING THE WORLD HEALTHY

Yangtze River Pharmaceutical (Group) Co., Ltd.

Jamjoom Pharmaceutical Co.,Ltd

Dongsung Pharm

Merck & Co, Inc.

L'Oreal France

Henkel

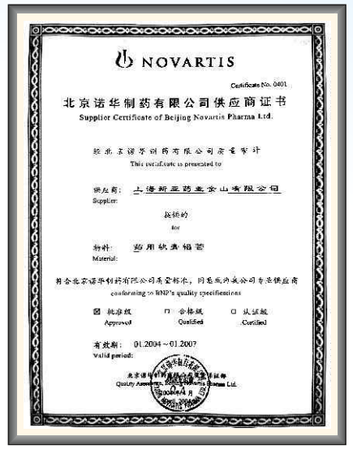
Napla Co.,Ltd

Hoyu Co.,Ltd.

MILBON JAPAN

Shiseido Professional

Qualified Supplier Certification
for Xian Janssen



Qualified Supplier Certification
for Novartis

Qualified Supplier Certification
for GSK

Excellent Supplier Certification
for Bayer China

2016 YUNNANBAIYAO
PROJECT COHESION
AWARD

2016 YUNNANBAIYAO
EXCELLENT SUPPLIER
CERTIFICATION

JOHNSON JOHNSON
INNOVATION
COOPERATION AWARD

Aluminium Canister for pMDI

- ✓ 5052 Aluminium-magnesium alloy material, in line with medical standards
- ✓ Weight deviation within ±0.05g
- ✓ Deformation pressure greater than 230psi, burst pressure greater than 300psi
- ✓ compatible with all common valves available on the market
  can be used for the currently used HFA gases as well as for the new low GWP gases
- ✓ The company is certified by ISO9001 and ISO15378

Specification Instruction

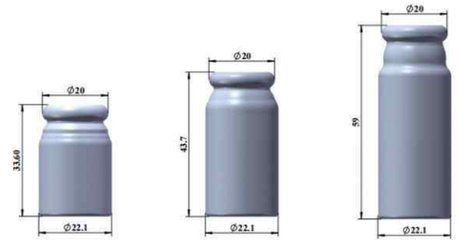
(Pressurized Metered-Dose Inhaler):pMDI Canister			
Name	Type Specification	Φmm	Can Length
pMDI Plain Cans 10ML	pMDI-A22.1/20*33.6-0.41	Φ22. 1	长33.6mm Length 33.6mm
pMDI Plain Cans 14ML	pMDI-A22.1/20*43.7-0.41	Φ22. 1	长43.7mm Length 43.7mm
pMDI Plain Cans 19ML	pMDI-A22.1/20*59-0.41	Φ22. 1	长59mm Length 59mm
pMDI FEP Coated Cans 14ML	pMDI-A22.1/20*43.7-0.61-FEP	Φ22. 1	长43.7mm Length 43.7mm
pMDI FEP Coated Cans 19ML	pMDI-A22.1/20*61-0.61-FEP	Φ22. 1	长61mm Length 61mm

For example：pMDI- A 22.1 / 20 X 33.6/61 - 0.61 - FEP

1. pMDI–Pressurized Metered-Dose Inhaler
2. A–ALU Represented as aluminum can is 5052 alloy aluminum
3. 22.1–Outer Diameter in mm
4. 20–means aerosol can inner necking diameter(mm)
5. 33.6/61–means aerosol can length(mm)
6. 0.61–means wall thickness (mm)
7. FEP–FEP(Fluorinated Ethylene Polymerisation)

Plain aluminium canister for pMDI

- ➢ Specification:10ml、14ml、19ml
- ➢ Strict weight control
- ➢ Scientific and strict control of mouth size to ensure airtightness



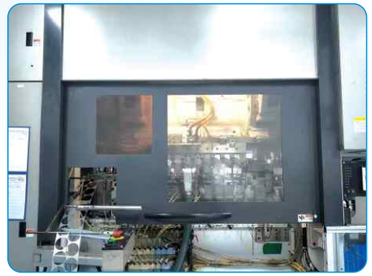
The disadvantages of Plain cans

- ➢ The hazards of Al element. it may cause ion migration, leadind to drug decradation, and there are also risks of toxicity to the nervous system and respiratory system.
- ➢ Hazards of Mg and Fe elements: They catalyze the Fenton/ Fenton-like reaction to produce reactive oxygen free radicals accelerating the oxidation and degradaion of drugs. At the same time, there are risks of toxicity to the nervous system and respiratory system.
- ➢ Drug adsorption: The high surface energy of bare tanks is prone to cause drug adsorption, which affects the actual dosage used.

FEP coated canister for pMDI

- ➢ Specification：14ml、19ml
- ➢ Excellent insulating properties, conductivity less than 30mA
- ➢ Reduced Drug Adhesion
- ➢ Inert Drug Contact Surface
- ➢ Non-porous Surface
- ➢ Low Surface Energy

Precision Manufacturing + Deep Drawing Process + Deep Cleaning



Deep Drawing Machine

Deep Degreasing Vacuum Cleaning Machine

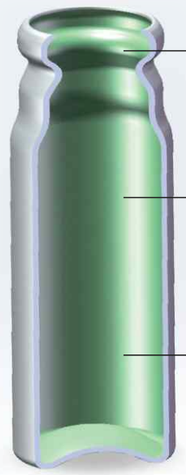
High-efficiency six-bucket Cleaning Machine

ISO 7 Grade Cleanroom

Advanced Spraying Technology

The bare cans are first stretched into shape, and then thoroughly cleaned.

The FEP coating treatment produces a continuous and stable fluorinated ethylene-propylene copolymer isolation layer on the inner surface of the canister.



The surface treatment fully replicates the contours of the can

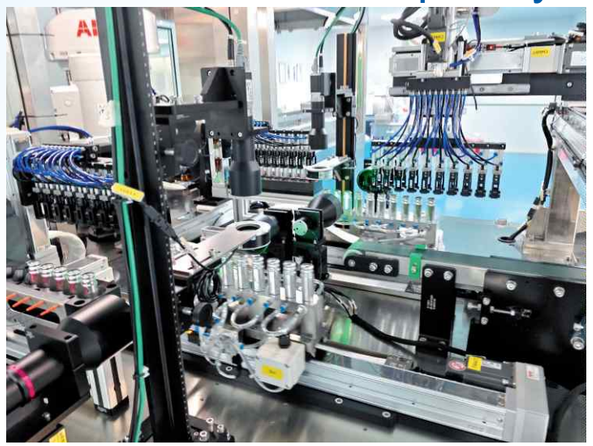
Fluorine coating provides an inert barrier between the can and the formulation, preventing drug degradation

Fluorine coating ensures the active drug content does not stick to the canister walls

Axial Scanner
Stretching process control to ensure dimensional and shape control during the stretching process

Comprehensive & Advanced Quality Process Control

15+ High-definition Cameras Comprehensive and Completely Unobstructed View



The online AI visual inspection equipment can conduct comprehensive and non-restrictive inspections on the appearance, size, and foreign objects of products, and eliminate any defective products.

Manual Re-inspection Double Guarantee

Manual External Surface Inspection

Manual Internal Surface Inspection

Low Leakage rate- Good Fit with the Valve

The laboratory is equipped with advanced Pamasol sealing machines, filling machines and a rapid leak rate detection mass spectrometer, which are used for the research on the airtightness of aluminum cans, ensuring that the experimental data are more accurate and precise.

Pamasol Crimp Measuring Gauge

Pamasol Crimp Valve Machine

Airtightness research (Slow leakage rate tests for 3 months and 6 months)				
Manufacturer	Type	Crimp valve height	Crimp valve diameter	Conclusion
Aptar	Df316	5.8±0.1	18±0.1	✓
	DF316Hybrid	5.8±0.1	18±0.1	✓
	DF30Plus	5.5±0.1	18±0.1	✓
RxPACK	Lindal	5.6±0.1	18±0.1	✓
	Coster	8.4±0.1	18±0.1	✓
Huarui	DR	5.6±0.1	18±0.1	✓
	DVH	8.2±0.1	18±0.1	✓
	DVH + LPS	8.2±0.1	18±0.1	✓

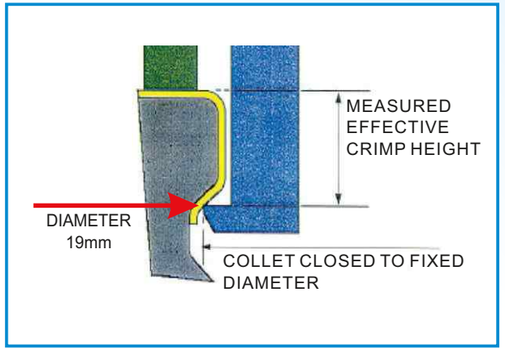
Filling Machine

High-speed Leakage Rate Detection Mass Spectrometer

Analysis of Leakage Phenomenon and Causes

➢ Analysis of Factors Related to Canisters

1. Total height of aluminum can & can mouth pressure
2. Neck height and shape
3. Aluminum can size consistency
4. Mouth flatness (cut burrs, mouth damage)



➢ Failure of Valve Components

1. Positioning cover size and thickness tolerance
2. Gasket thickness tolerance and surface flatness

➢ Filling Equipment Adaptation &The Significance of Valve Manufacturer's Guidance on Size

➢ Check Weight

Stable and accurate;Long duration and need to be measured regularly.

➢ Water Bath Testing

Can distinguish between valve leakage or leakage at the junction of the valve and aluminum can; About a week.

➢ MS Leakage Rate

Fast;However, it may not reflect the leakage situation after long-term storage. It is necessary to confirm it again by combining the weighing method.

➢ Leakage Investigation

Water Bath Testing Method

Leakage at The Valve Stem

Leakage Between Valve And Aluminum Can

Double Tube Gas Detection Measuring Cup

Valve Sealing Equipment and Valve Sealing Process Factors

Pamasol Crimp Valve Machine

Crimp valve process

Crimp valve height

Crimp valve diameter

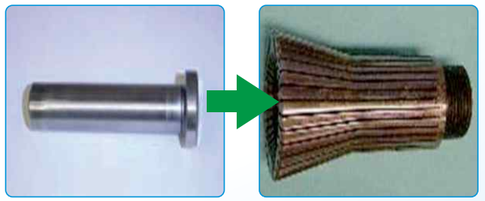
Adjusting height

Valve Clamp

Crimp Process

Pamasol Crimp Measuring Gauge

Direct Measurement



Indirect Measurement

Better Physical Properties, Chemical Resistance, and Lower Adhesion Performance

FEP Coated Cans Performance		
Classification	Experiment	Conclusion
Physical properties	Adhesion of the inner coating	✓
	Continuity of the inner coating	✓
Chemical resistance	Wipe with acetone	✓
	Copper sulphate test	✓
	HFA 134a propellant pMDI filling	✓
	HFA 152a propellant pMDI filling	✓
	HFO 1234ze propellant pMDI filling	✓
Drug adhesion	Dyne test	✓
	Contact angle test	✓
	Research on aerosol adhesion	✓

HPLC(High Performance Liquid Chromatograph)

Copley Anderson Cascade Impactor

Examples of formulations that benefit from FEP coated cans

Preparation		Applicable pressure can	
		Plain cans	FEP Coated cans
Single -component preparation	Salbutamol	✓	✓
	Levalbuterol	×	✓
	Beclometasone	✓	✓
	Cromolyn Sodium	✓	✓
	Ciclesonide	✓	✓
	Budesonide	×	✓
	Ipatropium Bromide	S.S.can	✓
	Formoterol	✓	✓
	Fluticasone	✓	✓
	Fenoterol Hydrobromid	×	✓
	Tiotropium	×	✓
	Nitroglycerine	×	✓
	Epinephrine	×	✓
Two -component formulation (Two-APIs)	Salbutamal+Ipratropium	×	✓
	Salbutamal+Fluticasone	×	✓
	Salbutamal+Beclomethasone	×	✓
	Budesonide+Formoterol	×	✓
	Mometasone+Formoterol	×	✓
	Fluticasone+Formoterol	×	✓
	Beclomethasone+Formoterol	×	✓
	Tiotropium+Formoterol	×	✓
	Glycopyronium+Formoterol	×	✓
	Fenoterol+Ipratropium	×	✓
Tripartite formulation (Three-APIs)	Circlesonide+Tiotropium+Formoterol	×	✓
	Beclomethasone+Formoterol+Glycopyronium	×	✓
	Budesonide+Formoterol+Glycopyronium	×	✓
	Fluticasone+Formoterol+Glycopyronium	×	✓

Quality Control Testing and Performance

Continuity of the inner coating	Physical properties
Wipe with acetone Copper Sulphate Test	Chemical resistance
Dyne Test Contact Angle Test Research on Aerosol Adhesion	Drug adhesion

Wipe with acetone

- Cut open the aluminum can and gently rub the inner coating back and forth with an acetone wiper for no less than 200 times;
- Observe whether there is any peeling or obvious whitening. There should be no peeling or obvious whitening.

Solvent-resistant Wipe Meter

The FEP and FCP coated were wiped with acetone 200 times

Continuity of the inner coating (Conductivity test)

- Using an inner coating continuity tester, place the aluminum tube into the suitable electrode to ensure that there is a circuit between the sample and the electrode;
- Insert the impregnating electrode into the center of the tube until it touches the tube shoulder. After inserting the electrode, inject the electrolyte into the aluminum tube to a distance of 10mm from the opening (tube end). After measuring the interval, read the data in mA.

Conductivity Meter

Comparison of conductivity values between FEP coated and FCP coated(mA)

Number	FEP coated cans (mA)			FCP coated cans(mA)		
1	0.08	0.26	0.24	4.35	4.76	4.37
2	0.10	0.08	0.50	5.30	40.97	3.06
3	0.15	0.08	0.15	2.51	3.91	2.27
4	0.09	0.15	0.14	3.35	3.79	4.93
5	0.23	0.08	0.09	11.12	6.18	6.61
6	0.25	0.16	0.26	2.98	45.0	3.0
7	0.09	0.07	0.20	7.17	8.09	3.37
8	0.23	0.07	0.13	4.46	3.47	4.91
9	0.09	0.10	0.17	1.11	2.15	5.70
10	0.27	0.13	0.24	39.75	33.25	3.02
Average value	0.163			9.164		
STD,%	0.09			12.46		

Copper Sulphate Test

- Pour the copper sulfate solution into the coating can and the plain can and wait for some time;
- Coating cans do not react with copper sulfate compared to plain can.

Placed for 4 hour

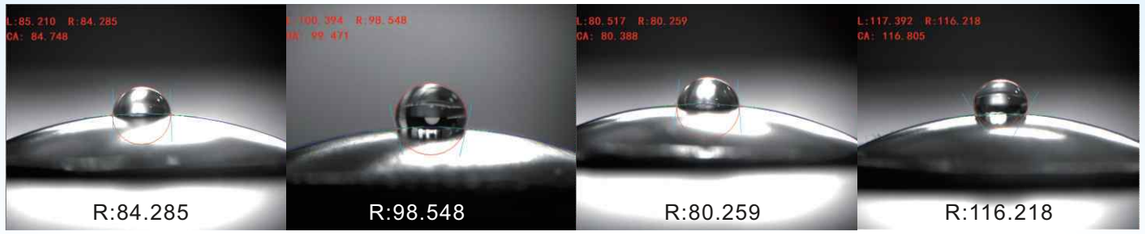
Plain cans | FCP coated cans | Plain cans | FEP coated cans

Dyne Test

Plain cans | FCP coated cans | Plain cans | FEP coated cans

- Compared to plain can or FCP can, Coating can are not wetted and show low surface energy

Contact Angle Test

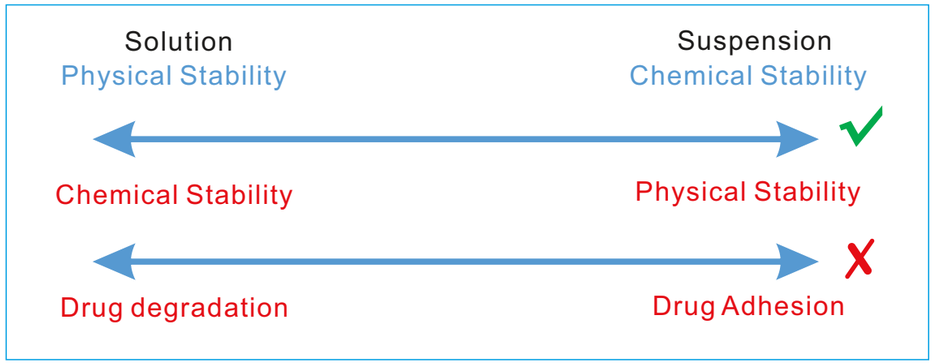


Plain cans | FCP coated cans | Plain cans | FEP coated cans

- Using a tensiometer test, drop water onto the can;
- The water droplets on coating can are rounder and therefore have a larger contact angle than plain can or FCP can.

Research on Aerosol Adhesion

The main influencing effects of different types of aerosols



Adhesion test

The adsorption of active pharmaceutical ingredients or functional excipients in packaging systems is commonly reported, which can not only lead to the reduction of drug quality, but also lead to changes in the physical and mechanical properties of materials, such as changing the softness, hardness, brittleness and so on. In general, Adhesion test can be combined with accelerated and stability tests of formulations.

Compatibility Study

Extractables and leachables (E&L)

FEP coated Compatibility Benefit VS Other Cans

1. Extraction and migration of metal ions

Ion Migration → Ionic Interaction → Drug Degradation

According to the ICHQ3D research(μg/ml)

Element	AET	FEP coated cans	FCP coated cans	Plain cans
(Cd)	0.90	<0.005	<0.005	<0.005
(Pb)	1.50	<0.005	<0.005	<0.005
(As)	0.60	<0.005	<0.005	<0.005
(Hg)	0.30	<0.005	<0.005	<0.005
(Co)	0.90	<0.005	<0.005	<0.005
(V)	0.30	<0.005	<0.005	<0.005
(Ni)	1.80	<0.005	<0.005	<0.005
(Tl)	2.40	<0.005	<0.005	<0.005
(Au)	0.90	<0.005	<0.005	<0.005
(Pd)	0.30	<0.005	<0.005	<0.005
(Ir)	0.30	<0.005	<0.005	<0.005
(Os)	0.30	<0.005	<0.005	<0.005
(Rh)	0.30	<0.005	<0.005	<0.005
(Ru)	0.30	<0.005	<0.005	<0.005
(Se)	39.00	<0.005	<0.005	<0.005
(Ag)	2.10	<0.005	<0.005	<0.005
(Pt)	0.30	<0.005	<0.005	<0.005
(Li)	7.50	<0.005	<0.005	<0.005
(Sb)	6.00	<0.005	<0.005	<0.005
(Ba)	90.00	<0.005	<0.005	<0.005
(Mo)	3.00	<0.005	<0.005	<0.005
(Cu)	9.00	<0.005	0.009	<0.005
(Sn)	18.00	<0.005	<0.005	<0.005
(Cr)	0.90	<0.005	0.02	<0.005

pH3 Acidic Solution Extraction - Data Source - Shanghai Institute for Food and Drug Packaging Materials Testing

Test result of formula element extraction, unit:μg/mL extract

Element	FEP coated cans	FCP coated cans	Plain cans
Aluminum	0.5 √	14.8	11
Ferrum	＜0. 01 √	0.01	0.02
Magnesium	＜0. 05 √	5.6	8.8
Manganese	＜0. 05 √	＜0. 05	＜0. 05
Silicon	＜0. 05 √	0.41	＜0. 05
Titanium	＜0. 01 √	＜0. 01	＜0. 01
Zinc	＜0. 01 √	0.88	＜0. 01

pH3 Acidic Solution Extraction - Data Source - Shanghai Institute for Food and Drug Packaging Materials Testing

2. Extraction of organic residues

Raw Materials → Cleaning Agent → Process Degradation

	Volatile Organic Compounds	Non-volatile Organic Compounds	
Testing Method	HS-GCMS(50-550m/z)	Direct Injection-GCMS (30-500m/z)或LCMS	
Plain cans	No Detected	No Detected	✓
FCP coated cans	No Detected	No Detected	✓
FEP coated cans	No Detected	No Detected	✓

Ethanol Extraction - Data Source - Shanghai Institute for Food and Drug Packaging Materials Testing