

Tofflon 东富龙	笔式注射器用卡式瓶系统 检验报告	生效日期	2025.10.23
	SMP-ZL-016 (01) R08	版本号	03

检品名称	笔式注射器用卡式瓶系统	报告日期	2026.08.20
批 号	KK251001	批 量	1597pcs
规 格	3ml	取样日期	2026.08.06
生产日期	2025.10.20	有效期至	2028.09
灭菌日期	2026.08.05	灭菌批号	26080511
产品编码	K-03-103		
检验依据	笔式注射器用卡式瓶系统质量标准和检验操作规程 (STP-A-012)		
检测项目	标准规定	检验结果	
硅油量	规格 (标示容量 3ml) : $\leq 0.2\text{mg}$	0.05mg/支, 符合规定	
密封性	应无穿过活塞或垫片的液体泄漏	符合规定	
自密封性	垫片穿刺部位应无液体泄漏	符合规定	
穿刺落屑	不得过 3 粒	0 粒, 符合规定	
滑动性能	起始力应 $\leq 10\text{N}$, 滑动力最大力应 $\leq 7\text{N}$, 平均滑动力应 $\leq 4\text{N}$	起始力: 2.503N, 滑动力最大力: 4.454N, 平均滑动力: 2.796N, 符合规定	
环氧乙烷残留量	$< 5\mu\text{g}/\text{个}$	未检出, 符合规定	
不溶性微粒	$\geq 10\mu\text{m}$ 的微粒: 不得过 60 粒/支; $\geq 25\mu\text{m}$ 的微粒: 不得过 6 粒/支	$\geq 10\mu\text{m}$ 的微粒: 12.2 粒/支; $\geq 25\mu\text{m}$ 的微粒: 0.4 粒/支; 符合规定。	
细菌内毒素	$< 0.125\text{EU}/\text{ml}$	$< 0.125\text{EU}/\text{ml}$, 符合规定	
无菌	应符合规定	符合规定	
特卫强封纸剥离性能	剥离强度: 应 $\geq 0.8\text{N}$. 剥离性能: 不过焊、胶转移连续且不花边、 四边热合宽度应基本一致。	剥离强度: 1.228N; 剥离性能: 符合规定; 符合规定	

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呼吸袋热合强度	所有样条的热合强度均 $\geq 1.5\text{N}/15\text{mm}$ 15.043N/15mm, 符合规定		
结论	根据《笔式注射器用卡式瓶系统质量标准和检验操作规程》(STP-A-012) 检验以上项目, 检验结果符合规定		
报告人		审核人	

Tofflon 东富龙	Pen Injector Cartridge System Inspection Report	Effective Date	2025.10.23
	SMP-ZL-016 (01) R08	Version No.	03

Product Name	Pen Injector Cartridge System	Report Date	2026.08.20
Batch No.	KK251001	Batch Quantity	1597 pcs
Specification	3 mL	Sampling Date	2026.08.06
Manufacturing Date	2025.10.20	Expiry Date	2028.09
Sterilisation Date	2026.08.05	Sterilisation Batch No.	26080511
Product Code	K-03-103		
Inspection Basis	Quality Standard and Inspection Operating Procedure for Pen Injector Cartridge Systems (STP-A-012)		
Test Item	Acceptance Criteria	Inspection Result	
Silicone Oil Quantity	Specification (labelled capacity: 3 mL): ≤ 0.2 mg	0.05 mg/unit; complies	
Seal Integrity	No liquid leakage through the piston or gasket	Complies	
Self-Sealing Performance	No liquid leakage at the gasket puncture site	Complies	
Puncture Coring	No more than 3 particles	0 particles; complies	
Gliding Performance	Break-loose force ≤ 10 N; maximum gliding force ≤ 7 N; average gliding force ≤ 4 N	Break-loose force: 2.503 N; maximum gliding force: 4.454 N; average gliding force: 2.796 N; complies	
Ethylene Oxide Residue	< 5 $\mu\text{g}/\text{item}$	Not detected; complies	
Insoluble Particulate Matter	Particles ≥ 10 μm : ≤ 60 particles/unit; particles ≥ 25 μm : ≤ 6 particles/unit	Particles ≥ 10 μm : 12.2 particles/unit; particles ≥ 25 μm : 0.4 particles/unit; complies	
Bacterial Endotoxins	< 0.125 EU/mL	< 0.125 EU/mL; complies	
Sterility	Shall comply	Complies	
Tyvek Seal-Paper Peel Performance	Peel strength ≥ 0.8 N. Peel performance: no over-sealing; adhesive transfer shall be continuous with no ragged edges; heat-seal width on all four sides shall be substantially uniform.	Peel strength: 1.228 N; peel performance: complies; complies	

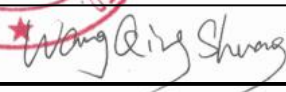
Tofflon 东富龙	Pen Injector Cartridge System Inspection Report	Effective Date	2025.10.23
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Breathable Pouch Heat-Seal Strength Heat-seal strength of all specimens ≥ 1.5 N/15 mm 15.043 N/15 mm; complies			
Conclusion	According to the Quality Standard and Inspection Operating Procedure for Pen Injector Cartridge Systems (STP-A-012), the above items were inspected. The inspection results comply with the specified requirements.		
Reported by		Reviewed by	

	<u>Cartridge system inspection report</u>	Effective Date	2025.10.23
	SMP-ZL-016 (01) R08	Version	03

Product	Cartridge system	Report date	2026.08.20
Batch number	KK251001	Total quantity	1597pcs
Size	3ml	Sample date	2026.08.06
Production date	2025.10.20	Expiration date	2028.09
Sterilization date	2026.08.05	Sterilization lot number	26080511
Product Code	K-03-103		
inspection standard	Quality standards and inspection procedure for cartridge systems for pen syringes (STP-A-012)		
Items	Acceptance criteria	Result	
Appearance	It should be a colorless transparent or brown transparent glass sleeve equipped with an aluminum cover containing a gasket (composite aluminum cover); The surface of the sleeve should be smooth and flat, and there should be no cracks and other obvious glass defects; The composite aluminum cover should be capped in place, and the surface of the aluminum cover should be flat, and there should be no any cosmetic defects that affect the sealing of the product	Meet the standard	
The amount of silicone oil	Comply with quality standards	0.05mg/vial, Meet the standard	
Tightness	It should be no leakage of liquid through the piston or gasket	Meet the standard	
Self-sealing	It should be no liquid leakage at the gasket puncture site	Meet the standard	
Puncture falling chips	No more than 3 capsules	0 capsules, Meet the standard	
Gliding performance	The starting force should be $\leq 10N$; the maximum sliding force should be $\leq 7N$; and the average sliding force should be $\leq 4N$	The starting force: 2.503N, the maximum sliding force: 4.454N, the average sliding force: 2.796N, Meet the standard	

	<u>Cartridge system inspection report</u>	Effective Date	2025.10.23
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Ethylene oxide residue	$\leq 5\mu\text{g/vial}$	Not detected, Meet the standard
Insoluble particles	$\geq 10\mu\text{m}$: NMT 600/vial; $\geq 25\mu\text{m}$: NMT60/vial	$\geq 10\mu\text{m}$ particle: 12.2 particle/vial; $\geq 25\mu\text{m}$ particle: 0.4 particle/vial; Meet the standard
Bacterial endotoxin	$< 0.125\text{EU/ml}$	Qualified
Sterile	should be Sterile	Qualified
Tyvek sealer peel performance	Peel strength: $\geq 0.8\text{N}$. Peel performance: It should not be over-welded, and the peeling surface should be flat and continuous	Peel strength: 1.228N; Peel performance: Meet the standard; Meet the standard
Conclusion	The above items were tested 《Quality standards and inspection procedure for cartridge systems for pen syringes》(STP-A-012), and the test results were in conformity with the regulations	
Reporter		Reviewer 

Dear Customers,

Triumph Junheng Co., Ltd (referred to as "Triumph"), Sichuan Tofflon Pharmaceutical Packaging Co., Ltd (referred to as "Tofflon"), and Jinan Munan Import & Export Co., Ltd (referred to as "Munan") are subsidiaries under the same group.

- The subsidiary company Triumph produces pharmaceutical glass tubes and glass vials (non-sterile)
- Tofflon, a subsidiary and China's top producer of pharmaceutical cleaning and filling equipment, has jointly invested with Triumph to establish an automatic production line for cleaning and drying vials, utilizing its own equipment, and conducted sterile processing.
- The subsidiary "Munan" are responsible for importing raw materials and exporting finished products for the group company

The Protocol for non-sterile vials are subject to Triumph's standards

The Protocol for sterile penicillin bottles are subject to Tofflon's standards

we apologize for any inconvenience caused.

Regard,
Sylvia

Triumph Junheng Co., Ltd
Sichuan Tofflon Pharmaceutical Packaging Co., Ltd
Jinan Munan Import & Export Co., Ltd



Certificate CN24/00006490

The management system of

Sichuan Tofflon Pharmaceutical Packaging Co., Ltd.

SGS

Building 1, No. 1000, Qihuang 1st Road, Tianfu International Bio-Town, Chengdu, Sichuan, P.R. China

has been assessed and certified as meeting the requirements of

ISO 15378:2017

Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2015 with reference to Good Manufacturing Practices (GMP)

For the following activities

Manufacture of primary packaging materials for pharmaceutical products (for export sales), including sterile cyclic olefin polymer (COP) assemblages for prefilled syringes, sterile cyclic olefin polymer (COP) vials for injection, sterile injection vials made of middle borosilicate glass tubing, sterile cartridge systems for pen-injector

The responsibility for the quality of the individual batches of the primary packaging materials for medicinal products manufactured, packed and stored lies with the organization
This certificate is valid from 08 October 2025 until 13 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 14 October 2024



Authorised by

Ben Tsang

SGS Hong Kong Limited

Units 303 & 305, 3/F., Building 22E, Phase 3, Hong Kong Science Park, New Territories, Hong Kong

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DMF 038735

DMF ACKNOWLEDGEMENT

SICHUAN TOFFLON PHARMACEUTICAL PACKAGING CO., LTD.
ATTENTION: YOUTING SHE, R&D DIRECTOR
618 FENGHUANG ROAD, TIANFU INTERNATIONAL BIO-TOWN
SHUANGLIU DISTRICT, CHENGDU, 610219
SICHUAN PROVINCE, P.R., CHINA

Dear Youting She,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

<u>DMF NUMBER ASSIGNED:</u>	038735
<u>DATE OF SUBMISSION:</u>	JULY 28, 2023
<u>DMF TYPE:</u>	III
<u>SUBJECT (TITLE):</u>	STERILE INJECTION VIALS MADE OF MIDDLE BOROSILICATE GLASS TUBING
<u>HOLDER:</u>	SICHUAN TOFFLON PHARMACEUTICAL PACKAGING CO., LTD.
<u>SUBMITTED BY:</u>	SICHUAN TOFFLON PHARMACEUTICAL PACKAGING CO., LTD.
<u>AGENT:</u>	NONE

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

Submissions in Paper (in two copies) or physical media should be sent to the following address.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville MD 20705-1266

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>.

The holder of the DMF is responsible for compliance with 21 CFR314.420 as interpreted in "The Guideline for Drug Master Files" at <https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf>.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
 - a. Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. (Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF (with DMF number) is not sufficient to authorize that party to reference the DMF).
 - b. Any change, addition or deletion of information.
 - c. Annual Reports containing:
 - i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
 - ii. A complete list of all parties currently authorized to incorporate information in the DMF by reference; identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
 - iii. A list of all parties whose authorization has been withdrawn, if applicable.
 - iv. Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it. Any change, addition or deletion of information will be notified to the FDA and to the authorized party.

You have an option to convert existing Type III paper DMF to eCTD. See FDA eCTD Web Page¹ and Guidance for Industry on electronic submissions² for information.

Note: If you have submitted a Letter of Authorization (LoA) without a DMF number, please resubmit the LoA with the DMF number.

For question on DMF submissions, send an email to dmfquestion@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

David Skanchy, Ph.D.

Director, Division of Lifecycle API

Office of Pharmaceutical Quality

Center for Drug Evaluation and Research

¹ See FDA eCTD Web Page for further information. <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>

² Section 745A(a) of the Food, Drug, and Cosmetic Act. See “Guidance for Industry: Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” (April 2017). <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CLAUDE THEOPHIN
08/16/2023 12:06:29 PM

