

Jiuyan Zhengyu Industrial Co., Ltd

CERTIFICATE OF ANALYSIS



Product	Sterile Neutral Borosilicate Tubular Glass Vial	Specification	3ml Clear	Package	320pcs/carton
Batch No.	ZY26061601	Batch Quantity		Number of samples	50pcs
Production date	2025-6-11	Inspection date	2026-6-18	Report date	2026-6-28
Standards	ISO8362, ISO11135, E.U.P., U.S.P.		Sampling plan	GB/T2828.1-2012 normal inspection once sampling plan	

Inspection items		Technical requirements	Inspection level (IL)	AQL value	n/Ac	Defective products quantity	Testing result	Conclusion
Appearance	Glass defect	The surface should be smooth and flat, and there should be no obvious glass defects	I	4.0	315/21	0	The surface of the tested sample is smooth and flat, without obvious glass defects	Qualified
	Color	Transparent				0	The tested sample is colorless and transparent	Qualified
	Crack	No cracks in any part	I	0.65	315/5	0	No cracks in any part of the sample	Qualified
Dimension	Body diameter	16.0mm±0.15mm	I	2.5	315/14	0	15.92mm～16.11mm	Qualified
	O.D. of mouth	13.0mm±0.2mm				0	12.83mm～13.17mm	Qualified
	I.D. of mouth	7.0mm±0.2mm				0	6.88mm～7.05mm	Qualified
	Overall height	35.0mm±0.5mm				0	35.75mm～36.25mm	Qualified
	Mouth thickness	3.6mm±0.2mm				0	3.51mm～3.66mm	Qualified
	Body thickness	1.0mm±0.04mm	S-3	2.5	32/2	0	0.97mm～1.03mm	Qualified
	Bottom thickness	≥0.7mm				0	0.7mm～1.0mm	Qualified
	Vertical axis deviation	a _{max} （mm）≤1.0				0	0.3mm～0.5mm	Qualified
Internal stress		After annealing, the largest optical path difference caused by the permanent stress shall not exceed 40nm/mm.	S-1	1.5	8/0	0	5nm/mm～12nm/mm	Qualified
Heat resistance		shall not rupture	S-3	0.65	32/0	0	No rupture	Qualified
Freezing resistance		shall not rupture				0	No rupture	Qualified
Physical and chemical properties			Technical requirements				Inspection result	Conclusion
Thermal expansion coefficient			3.5～6.1×10 ⁻⁶ K ⁻¹ (20-300℃)				5.0×10 ⁻⁶ K ⁻¹	Qualified
Content of B ₂ O ₃			≥8%				10.14%	Qualified
121℃ particles method water resistance			It shall comply with level 1				Level 1	Qualified
98℃ particles method water resistance			It shall comply with HGB level 1				HGB1	Qualified
Internal surface water resistance			It shall comply with HC level1				HC1	Qualified
Acid resistance			It shall comply with level 1				Level 1	Qualified

Alkali resistance		Should not be lower than level 2 requirements	Level 2	Qualified
Leaching amount of arsenic, antimony, lead, cadmium		As $\leq$ 0.2mg/L	<0.1mg/L	Qualified
		Sb $\leq$ 0.7mg/L	<0.1mg/L	Qualified
		Pb $\leq$ 1.0mg/L	<0.1mg/L	Qualified
		Cd $\leq$ 0.25mg/L	<0.1mg/L	Qualified
Wash and sterilization		Technical requirements	Inspection result	Conclusion
Appearance		The bottle body and inner wall are clean and tidy, no water marks	The body and inner wall of the sample bottle tested are clean and tidy, and there is no water trace	Qualified
Visible foreign body		No obvious foreign body shall be detected, and point-like objects, short cilia and lumps under 2mm (total should be $\leq$ 4)	0	Qualified
Residual amount of ethylene oxide		It should be <1 μ g/mL	<1 μ g/mL	Qualified
Bacterial endotoxin		It should be <20EU/product	<20EU/product	Qualified
Sterility test		The test tube is clear, or it is turbid but it has been confirmed that there is no bacterial growth	The test tube is clear	Qualified
Insoluble particles		$\geq$ 10 μ m, $\leq$ 60 pcs/vial $\geq$ 25 μ m, $\leq$ 6 pcs/vial	$\geq$ 10 μ m, 10.2 pcs/vial $\geq$ 25 μ m, 1 pcs/vial	Qualified
Inspection conclusion	This batch of products was inspected in strict accordance with the requirements of the national pharmaceutical packaging standards ISO8362, ISO11135, E.U.P., U.S.P, Chinese Pharmacopoeia. The results were qualified.			

Inspector/Date: Anjing 2025-6-27
Auditor/Date: Tongqianqian 2025-6-27

Reviewer /Date: Liutaizhou 2025-6-27



DMF 043450

DMF ACKNOWLEDGEMENT

JIYUAN ZHENGYU INDUSTRIAL CO., LTD.
ATTENTION: JINGYI ZHANG, MANAGER
NO. 869, 600 METERS WEST OF JINMA AVENUE
CHENGLIU TOWN, JIYUAN CITY
HENAN PROVINCE, CHINA

Dear Jingyi Zhang,

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

<u>DMF NUMBER ASSIGNED:</u>	043450
<u>DATE OF SUBMISSION:</u>	JANUARY 22, 2026
<u>DMF TYPE:</u>	III
<u>SUBJECT (TITLE):</u>	TUBULAR BOROSILICATE GLASS VIALS (INCLUDING STERILE AND NON-STERILE)
<u>HOLDER:</u>	JIYUAN ZHENGYU INDUSTRIAL CO., LTD.
<u>SUBMITTED BY:</u>	JIYUAN ZHENGYU INDUSTRIAL CO., LTD.
<u>AGENT:</u>	REACH24H USA INC

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.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
 - 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. Listing an authorized party in the Annual Report is not sufficient to authorize that party to reference 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 also not sufficient to authorize that party to reference the DMF.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

- Any change, addition or deletion of information
- Annual Reports to the DMF containing:
 - 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.
 - 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.
 - A list of all parties whose authorization has been withdrawn, if applicable.
 - Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it.

For specific information on DMF, including submission types, letter template examples, and links to other resources, please refer to the DMF webpage.¹

The holder of the DMF is responsible for compliance with 21 CFR 314.420 as interpreted on the Guideline for Drug Master Files webpage.²

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 additional information on electronic submission, see the FDA eCTD webpage and the guidance for industry *Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.^{3,4}

¹ <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>

² <https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf>

³ <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0>

Note: If you have submitted a LOA without a DMF number, please resubmit the LOA with the DMF number.

For any questions related to DMF submissions, please contact dmfquestion@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Don Henry
Director, Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CC:
REACH24H USA INC
ATTENTION: ROBERT KIEFER
11921 FREEDOM DR STE 550
RESTON, VA 20190

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
02/03/2026 02:03:55 PM

DMF 043452

DMF ACKNOWLEDGEMENT

JIYUAN ZHENGYU INDUSTRIAL CO., LTD.
ATTENTION: JINGYI ZHANG, MANAGER
NO. 869, 600 METERS WEST OF JINMA AVENUE
CHENGLIU TOWN, JIYUAN CITY
HENAN PROVINCE, CHINA

Dear Jingyi Zhang,

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

<u>DMF NUMBER ASSIGNED:</u>	043452
<u>DATE OF SUBMISSION:</u>	JANUARY 12, 2026
<u>DMF TYPE:</u>	III
<u>SUBJECT (TITLE):</u>	BOROSILICATE GLASS AMPOULES
<u>HOLDER:</u>	JIYUAN ZHENGYU INDUSTRIAL CO., LTD.
<u>SUBMITTED BY:</u>	JIYUAN ZHENGYU INDUSTRIAL CO., LTD.
<u>AGENT:</u>	REACH24H USA INC

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.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
 - 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. Listing an authorized party in the Annual Report is not sufficient to authorize that party to reference 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 also not sufficient to authorize that party to reference the DMF.
 - Any change, addition or deletion of information

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

- Annual Reports to the DMF containing:
 - 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.
 - 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.
 - A list of all parties whose authorization has been withdrawn, if applicable.
 - Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it.

For specific information on DMF, including submission types, letter template examples, and links to other resources, please refer to the DMF webpage.¹

The holder of the DMF is responsible for compliance with 21 CFR 314.420 as interpreted on the Guideline for Drug Master Files webpage.²

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 additional information on electronic submission, see the FDA eCTD webpage and the guidance for industry *Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.^{3,4}

Note: If you have submitted a LOA without a DMF number, please resubmit the LOA with the DMF number.

¹ <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>

² <https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf>

³ <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0>

For any questions related to DMF submissions, please contact dmfquestion@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Don Henry
Director, Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CC:
REACH24H USA INC
ATTENTION: ROBERT KIEFER
11921 FREEDOM DR STE 550
RESTON, VA 20190

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
01/27/2026 09:23:49 AM