CHANGZHOU DREURE MEDICAL MATERIAL CO.,LTD.
NO.7 JINHUA ROAD, WUJIN ECONOMIC DEVELOPMENT ZONE, CHANGZHOU, JIANGSU, CHINA.

Sample Description	: LDPE FILM/BAG FOR DRUG USE
SKU No.	: B2505310
Style No.	: 300*350*900*0.09mm
Manufacturer	: CHANGZHOU DREURE MEDICAL MATERIAL CO.,LTD.
Supplier	: CHANGZHOU DREURE MEDICAL MATERIAL CO.,LTD.
Country of Origin	: CHINA

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

SGS Ref No.	: TAOLSS25-00255.01/ SHMR250801726301
Sample Receiving Date	: Jul 09, 2025
Test Performing Date	: Jul 09, 2025 to Aug 12, 2025

Test Requested	Test Result
Identification A	Pass
Acidity or alkalinity	Pass
Absorbance	Pass
Total organic carbon	Pass
Differential Scanning Calorimetry*	Pass

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc… and just for internal reference.

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Scan to see the report
QDHL250600937001PK
Verification:
check.sgsonline.com.cn

Roxana Zhao
Authorized Signatory

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

Test Result(s):

Test/Parameter	Test Method	Result	Specification	Conclusion
Identification A	USP-NF<661.1> (Official Date: 01-Dec-2025)	The infrared spectrum of the sample is consistent with the reference spectrum	The infrared spectrum of the sample should be consistent with the reference spectrum	Pass
Acidity or alkalinity	USP-NF<661.1> (Official Date: 01-Dec-2025)	The volume of 0.01M sodium hydroxide titrant consumed to turn the indicator color blue is 0.04mL; the volume of 0.01M hydrochloric acid titrant consumed to change the indicator color from yellow to orange is 0.5mL	Not more than 1.5 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to blue; Not more than 1.0 mL of 0.01 M hydrochloric acid is required to initiate the colour change of the indicator from yellow to orange.	Pass
Absorbance	USP-NF<661.1> (Official Date: 01-Dec-2025)	Measure absorbance within the range of 220nm~340nm, with a maximum of 0.01	Measure absorbance within the range of 220nm~340nm, with a maximum not exceeding 0.2	Pass
Total organic carbon	USP-NF<661.1> (Official Date: 01-Dec-2025)	1 mg/L	≤5mg/L	Pass
Differential Scanning Calorimetry*	USP42<661.1>-2018	See appendix for details	See appendix for details	Pass

****

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

Appendix: Differential Scanning Calorimetry*

Sample Description: A-Plastic part,B-Plastic part

Test Method: USP42<661.1>-2018

Test Condition:

Type of sample container：Al

Purge gas flow rate (Nitrogen: 99.999%)：50ml/min；

Temperature range：40~200℃

Heating rate：10℃/min

Test Result:

Test item/Sample	Test result		Customer requirement	Conclusion
Melting Temperature (T_m)	Sample A (Specimen)	113.3℃	The difference in T_m between the specimen and the standard ≤6℃	Pass
	Sample B (Standard)	109.4℃		

Note: Sample A was basically consistent with sample B in DSC curves.

Original data:

Sample A

Test Item	First heating scan (DSC curve see Fig.1)	Second heating scan (DSC curve see Fig.2)
Melting extrapolated onset temperature, T*eim*	100.7℃	100.4℃
Melting peak temperature, T*pm*	113.3℃	111.8℃
Melting extrapolated end temperature, T*efm*	118.5℃	118.1℃

Sample B

Test Item	First heating scan (DSC curve see Fig.1)	Second heating scan (DSC curve see Fig.2)
Melting extrapolated onset temperature, T*eim*	98.6℃	103.2℃
Melting peak temperature, T*pm*	109.4℃	109.1℃
Melting extrapolated end temperature, T*efm*	112.7℃	112.1℃

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

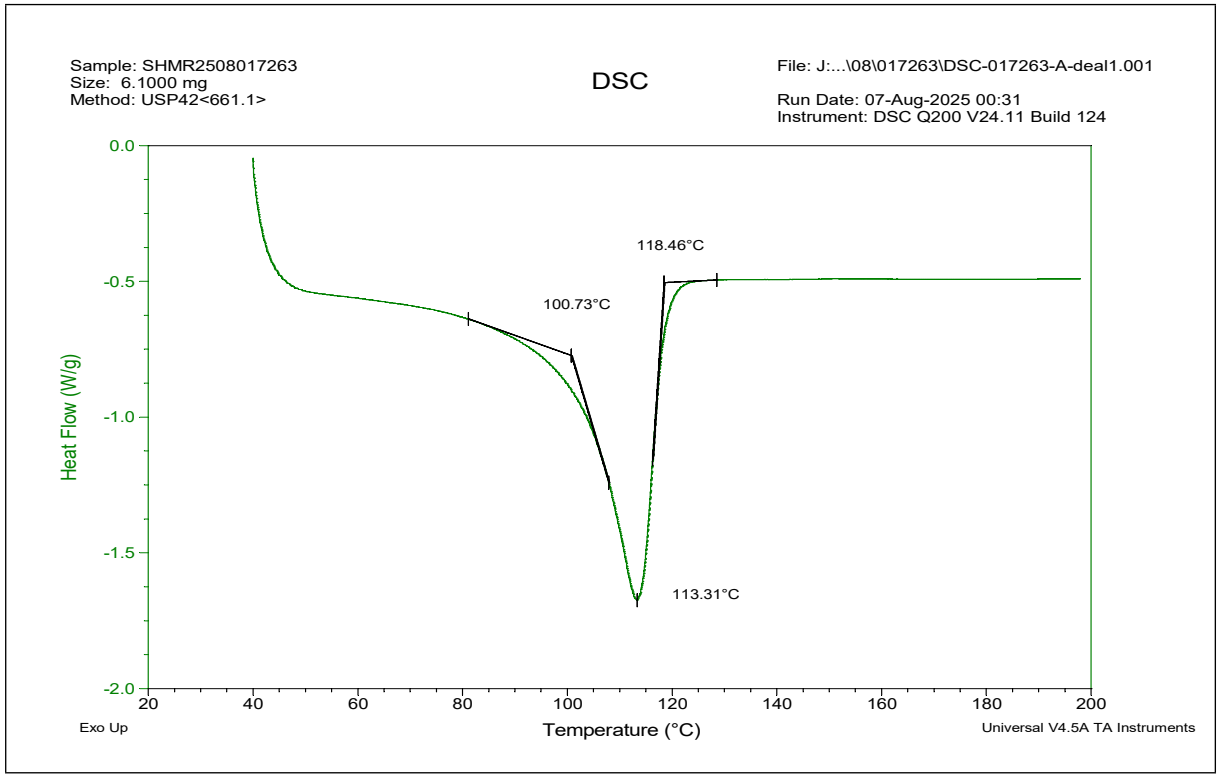
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

Member of the SGS Group (SGS SA)

Appendix

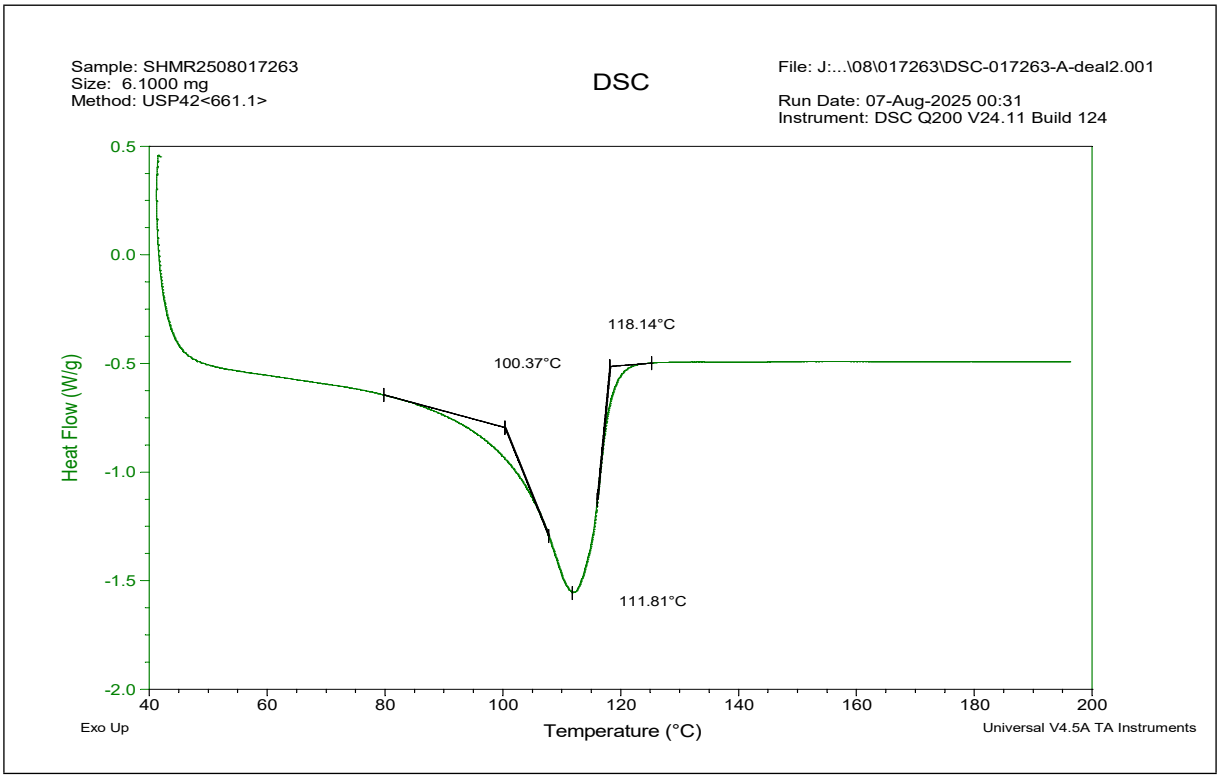
Sample A

Fig.1:



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

Fig.2:

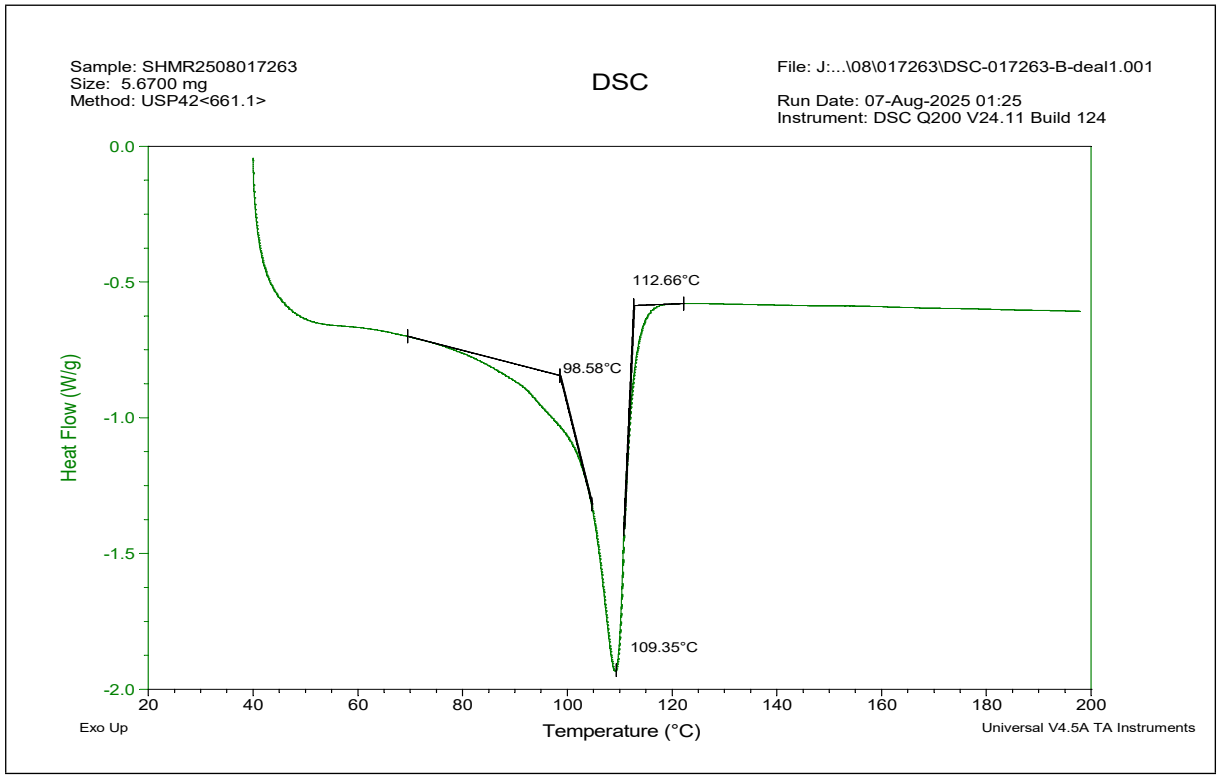


Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

Sample B

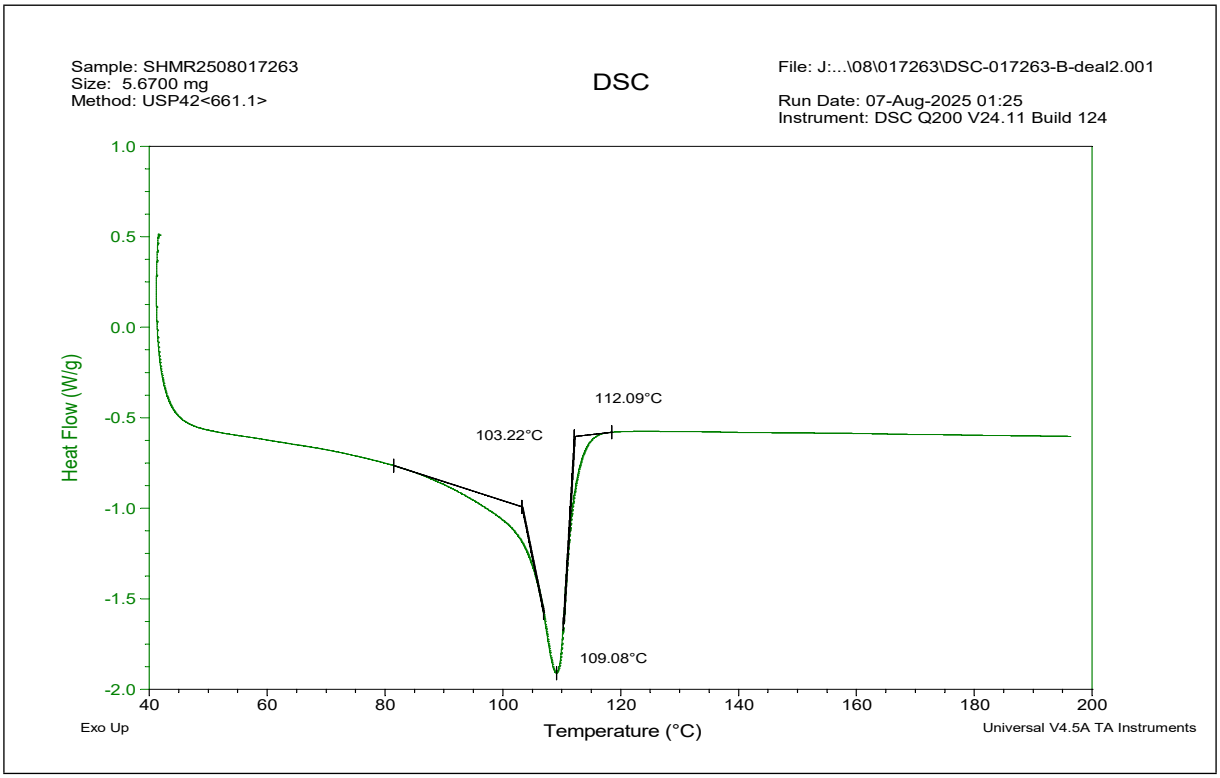
Fig.1:



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

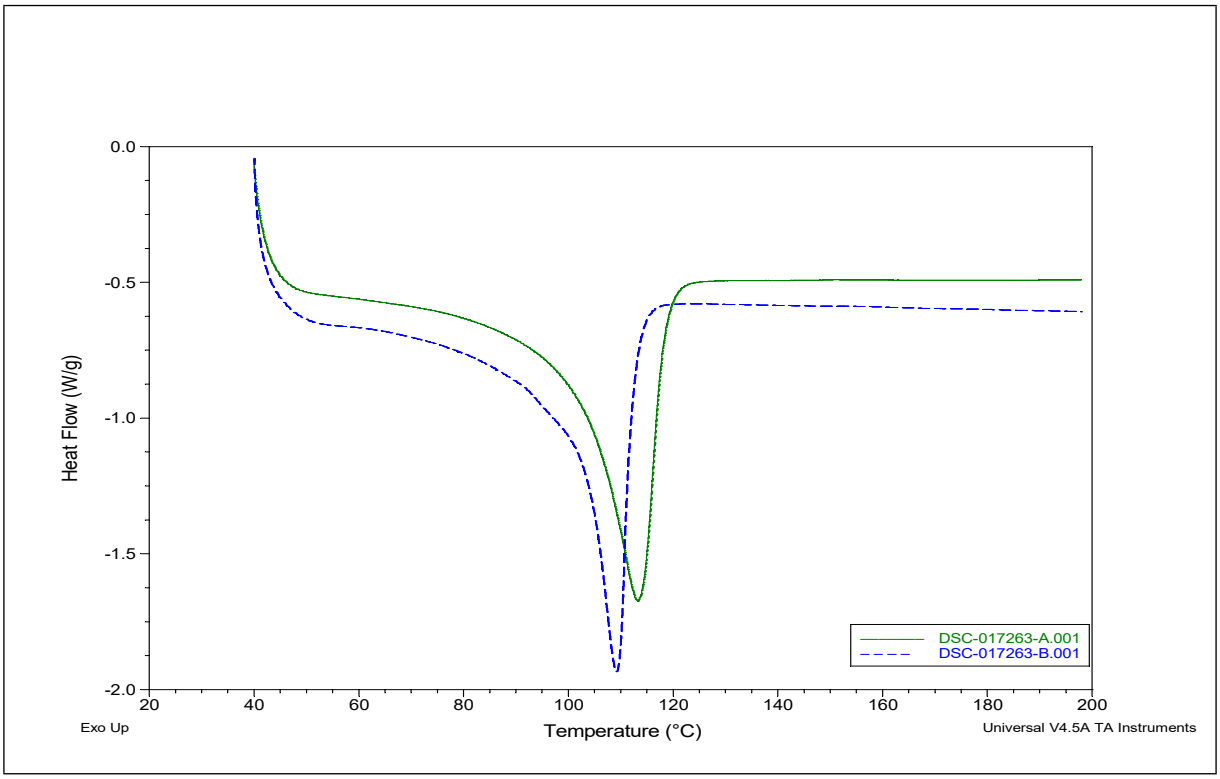
Fig.2:



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

Fig.3



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

Test Photo:

	
Original Sample-Sample A	Original Sample-Sample B

Equipment Information:

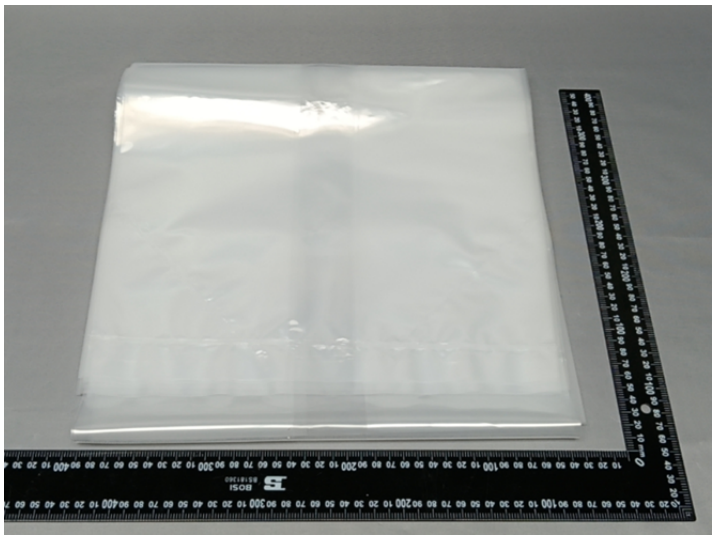
Equipment Name	Model	Equipment No.	Calibration date	Next Calibration date
Analytical Balance	XS105DU	P-98	2024-09-19	2025-09-18
Differential scanning calorimeter(DSC)	DSC Q-200	P-96	2025-08-05	2026-08-04

Remark:
- Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule (*w*=0) stated in ILAC-G8:09/2019.
- * Test was carried out by SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. (CMA No. 230920340938; CNAS No. L0599).

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com

Sample Photo:



SGS authenticate the photo on original report only

End of Report

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at https://www.sgs.com/en/Terms-and-Conditions. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.
Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn
中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 sgs.china@sgs.com