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202105-202304

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ADMINISTRATION Test Through MANTONG.

Panjin Zhongrun High Performance Polymers Co.,Ltd.

Fine Chemical Industry Zone, Wujia Town, Panshan country, Panjin, Liaoning

Product Description:	CoPEEK
Job No.	J-00392192
Test Method:	US FDA 21 CFR 177.2415
Test Laboratory	NSF International
Testing Completion Date	06-Apr-2021 ~ 13-Apr-2021
FDA Registration Number	12181305210



Jacky M Chuang

Executive Director

Date: 04.20.2021

MTG STANDARD TESTING & CERTIFICATION SERVICE CENTER www.fdacn.org

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Country ,Panjin,Liaoning

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Result Complete

Report Date 13-Apr-2021

Customer Name Panjin Zhongrun Performance Polymers Co., Ltd.

Description CoPEEK

Test Type Test Only

Product Material PEEK

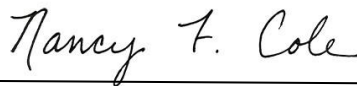
Job Number J-00392192

Sample Reception Date 06-Apr-2021

Testing Date 06-Apr-2021~13-Apr-2021

Summary of Results

Testing Parameters and Standards	Result
Determination of net chloroform soluble extractives according to US FDA 21 CFR 177.2415	Complete



Report Authorization

Date

16-Apr-2021

Nancy Cole - Director, Analysis Laboratories

1. **Determination of net chloroform soluble extractives according to US FDA 21 CFR 177.2415**

1.1 Testing procedure:

Extract samples at the extractive solvent and extractive condition, and weigh the extractives residue and calculate the contacted area of the samples. When total extractive result is already less than the chloroform soluble extractive limitation, then no further extractive testing is performed.

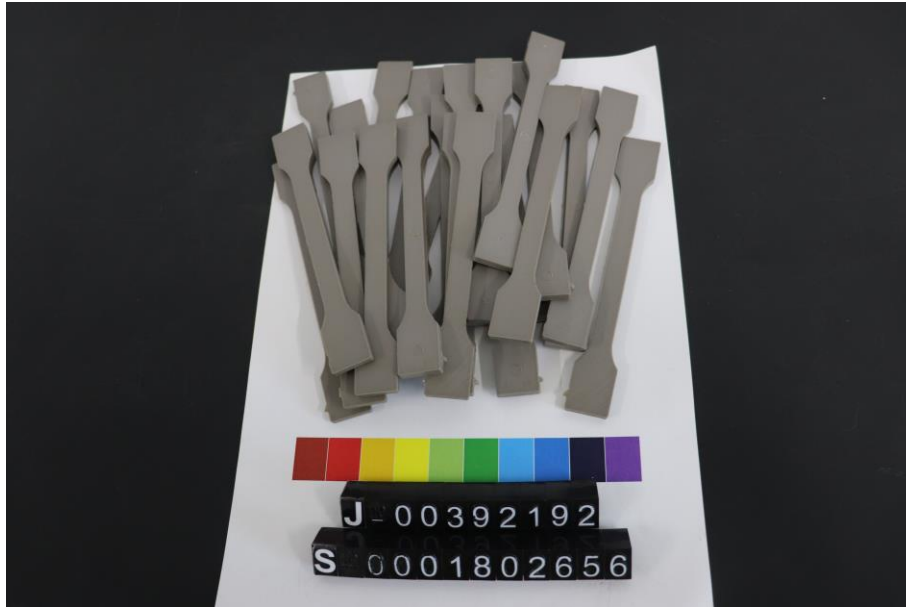
1.2 Testing results:

Sample No.	Testing Parameter	Testing condition	Unit	Result	Acceptance	Conclusion
S-0001802656	Total extractives (Water)	Reflux temperature,2h	mg/in ²	0.025	≤0.05	PASS
	Total extractives (3% Acetic acid)	Reflux temperature,2h	mg/in ²	0.028	≤0.05	PASS
	Total extractives (50% Ethanol)	Reflux temperature,2h	mg/in ²	0.049	≤0.05	PASS
	Total extractives (n-Heptane)	Reflux temperature,2h	mg/in ²	0.040	≤0.05	PASS

Remark

- 1) Client claim the material of sample is CoPEEK
- 2) End-product testing was performed to 21 CFR 177.2415 per Client request and that the acceptable results are based on the assumption that all material components have been confirmed by the formulator as compliant to 21 CFR and applicable FDA regulations for the intended end use.
- 3) Shanghai Laboratory was authorized by Ann Arbor to conduct the testing.

Picture of Sample



**CoPEEK
End of Report**