

Test Report

No.: SHAEC24013533601

Date: Jul 02, 2024

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Client Name: ANHUI PURUIKANG PHARMACEUTICAL PACKAGING TECHNOLOGY CO.,LTD.

Client Address: NO. 23 SCIENCE ROAD, SHUSHAN MODERN INDUSTRIALPARK, SHOUXIAN COUNTY, HUAINAN CITY ANHUI PROVINCE

Sample Name: PET WITH ALUMINUM

The above sample(s) and information were provided by the client.

SGS Job No.: SHP24-019896

Sample Receiving Date: Jun 21, 2024

Testing Period: Jun 21, 2024 ~ Jul 02, 2024

Test Requested: Select test(s) as requested by the client.

Test Method(s): Please refer to next page(s).

Test Result(s): Please refer to next page(s).

	Test Requirement	Comment
1	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Overall Migration	Pass
2	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of heavy metals	Pass
3	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of primary aromatic amine (total)	Pass
4	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of ethylene glycol and diethylene glycol (expressed as ethylene glycol)	Pass
5	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of terephthalic acid	Pass

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

Sue Sheng

Sue Sheng
Approved Signatory

scan to see the report



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Test Result(s):

Test Part Description:

SN ID	Sample No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	A.C001	SHA24-0135336-0001.C001	Golden/Silvery solid	PET+ALUMI NUM

Remarks:

- (1) mg/dm² = milligram per square decimeter
 mg/inch² = milligram per square inches
 µg/cm² = microgram per square centimeter
 mg/L = milligram per litre
 mg/kg = milligram per kilogram
- (2) °C = degree Celsius
 °F = degree Fahrenheit
- (3) <= less than
- (4) RL = Reporting Limit
- (5) ND = Not Detected (< RL).

The ratio of surface area to volume

Sample No	Overall Migration	Specific Migration
A.C001	10.0 dm ² /kg	6.0 dm ² /kg

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Overall Migration

Test Method: With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods; EN 1186-3:2022 Test methods for overall migration in evaporable simulants

Test Condition				
	10% Ethanol(V/V)	3% Acetic acid (W/V)	95% Ethanol	Isooctane
A.C001	70°C, 2 hrs	70°C, 2 hrs	60°C, 2 hrs	40°C, 0.5 hr

Simulant used	Limit	Unit(s)	RL	A.C001 (1 st Migration)	A.C001 (2 nd Migration)	A.C001 (3 rd Migration)	Stability	Comment
10% Ethanol(V/V)	10	mg/dm ²	3.0	ND	ND	ND	Compliant	Pass
3% Acetic acid (W/V)	10	mg/dm ²	3.0	ND	ND	ND	Compliant	Pass
95% Ethanol	10	mg/dm ²	3.0	ND	ND	ND	Compliant	Pass



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Simulant used	Limit	Unit(s)	RL	A.C001 (1 st Migration)	A.C001 (2 nd Migration)	A.C001 (3 rd Migration)	Stability	Comment
Isooctane	10	mg/dm ²	3.0	ND	ND	ND	Compliant	Pass

Notes:

- (1) Analytical tolerance of evaporable simulants is 2 mg/dm² or 12 mg/kg, analytical tolerance of olive oil simulant is 3 mg/dm² or 20 mg/kg.
- (2) Test condition & simulant were specified by client.
- (3) A material or article with overall migration result that exceeds the overall migration limit by an amount not exceeding the analytical tolerance, shall be deemed to be in compliance with the overall migration limit.
- (4) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of heavy metals

Test Method: With reference to EN 13130-1:2004, analysis was performed by ICP-OES/ICP-MS.

Simulant	Test Condition
3% Acetic acid (W/V)	A.C001 70°C, 2 hrs

Test Item(s)	Limit	Unit(s)	RL	A.C001		
3% Acetic acid (W/V)						
Migration times				First	Second	Third
Arsenic(As)	ND	mg/kg	0.01	ND	ND	ND
Cadmium(Cd)	ND	mg/kg	0.002	ND	ND	ND
Chromium(Cr)	ND	mg/kg	0.01	ND	ND	ND
Mercury(Hg)	ND	mg/kg	0.01	ND	ND	ND
Lead(Pb)	ND	mg/kg	0.01	ND	ND	ND
Aluminium(Al)	1	mg/kg	0.1	ND	ND	ND
Barium(Ba)	1	mg/kg	0.25	ND	ND	ND
Cobalt(Co)	0.05	mg/kg	0.01	ND	ND	ND
Copper(Cu)	5	mg/kg	0.25	ND	ND	ND
Iron(Fe)	48	mg/kg	5	ND	ND	ND
Lithium(Li)	0.6	mg/kg	0.1	ND	ND	ND
Manganese(Mn)	0.6	mg/kg	0.1	ND	ND	ND
Zinc(Zn)	5	mg/kg	0.5	ND	ND	ND
Nickel(Ni)	0.02	mg/kg	0.01	ND	ND	ND
Antimony(Sb)	0.04	mg/kg	0.01	ND	ND	ND
Europium(Eu)	-	mg/kg	0.025	ND	ND	ND
Gadolinium(Gd)	-	mg/kg	0.025	ND	ND	ND
Lanthanum(La)	-	mg/kg	0.025	ND	ND	ND
Terbium(Tb)	-	mg/kg	0.025	ND	ND	ND
Europium(Eu)+ Gadolinium(Gd)+ Lanthanum(La)+ Terbium(Tb)	0.05	mg/kg	-	ND	ND	ND
Stability	-	-	-	Compliant		



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Test Item(s)	Limit	Unit(s)	RL	A.C001
Comment				Pass

Notes:

- (1) Test condition & simulant were specified by client.
- (2) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. For substances which limit is "Not Detected", the compliance is based on the first migration test result if it is detected.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of primary aromatic amine (total)

Test Method: With reference to EN 13130-1:2004, analysis was performed by UV-Vis.

Simulant	Test Condition
	A.C001
3% Acetic acid (W/V)	70°C, 2 hrs

Test Item(s)	Limit	Unit(s)	RL	A.C001		
3% Acetic acid (W/V)						
Migration times				First	Second	Third
Specific migration of primary aromatic amine	0.01	mg/kg	0.002	ND	ND	ND
Stability	-	-	-	Compliant		
Comment				Pass		

Notes:

- (1) Test condition & simulant were specified by client.
- (2) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. For substances which limit is "Not Detected", the compliance is based on the first migration test result if it is detected.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of ethylene glycol and diethylene glycol (expressed as ethylene glycol)

Test Method: With reference to EN 13130-1:2004 and BS EN 13130-7:2004, analysis was performed by GC-FID.

Simulant	Test Condition
	A.C001
3% Acetic acid (W/V)	70°C, 2 hrs

Test Item(s)	Limit	Unit(s)	RL	A.C001		
3% Acetic acid (W/V)						
Migration times				First	Second	Third



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Test Item(s)	Limit	Unit(s)	RL	A.C001		
Specific migration of ethylene glycol	-	mg/kg	3	ND	ND	ND
Specific migration of diethylene glycol	-	mg/kg	3	ND	ND	ND
Sum of ethylene glycol and diethylene glycol (expressed as ethylene glycol)	30	mg/kg	-	ND	ND	ND
Stability	-	-	-	Compliant		
Comment	Pass					

Notes:

- (1) Test condition & simulant were specified by client.
- (2) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. For substances which limit is "Not Detected", the compliance is based on the first migration test result if it is detected.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation - Specific migration of terephthalic acid

Test Method: With reference to EN 13130-1:2004 and EN 13130-2:2004, analysis was performed by LC-DAD

Simulant	Test Condition
3% Acetic acid (W/V)	A.C001 70°C, 2 hrs

Test Item(s)	Limit	Unit(s)	RL	A.C001		
3% Acetic acid (W/V)						
Migration times				First	Second	Third
Specific migration of terephthalic acid	7.5	mg/kg	1.0	ND	ND	ND
Stability	-	-	-	Compliant		
Comment	Pass					

Notes:

- (1) Test condition & simulant were specified by client.
- (2) For repeated use, compliance of the material or article is verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. For substances which limit is "Not Detected", the compliance is based on the first migration test result if it is detected.

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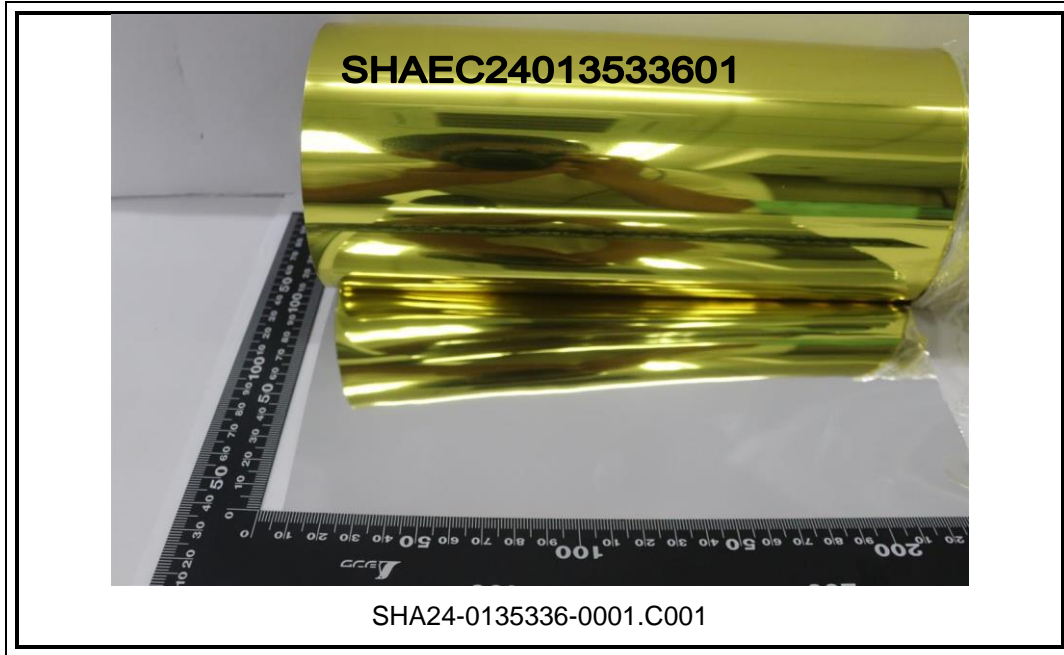
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