TEST REPORT

Applicant	:	Evodrop AG
Address	:	Hardgutstrasse 16, 8048 Zurich, Switzerland

Report on the submitted sample said to be

Sample name	:	EVOdescale
Model	:	N/A
Buyer	:	N/A
Manufacturer	:	Evodrop AG
Address	:	Hardgutstrasse 16, 8048 Zurich, Switzerland
Sample received date	:	Aug. 02, 2022
Testing period	:	Aug. 02, 2022 – Aug. 09, 2022
Test Result(s)	:	Please refer to the next pages

Signed For And On Behalf Of

Shenzhen ZTS Testing Service Co., Ltd

Lab Manager : **Bert Yang**

Aug. 09, 2022

Date of issue

Test Sample	Test Requested:	Conclusion
001 002 004	As requested by client, according to the FDA 21 CFR 177.1520, to Determine the Total Extractives for the submitted sample - Melting point - Density - Extractable fraction in n-Hexane - Extractable fraction in Xylene - it is for contact with food	Pass
003	FDA 21 CFR 177.2600 – Total extractives - Total extractives in Distilled water - Total extractives in n-Hexane	Pass
005	As requested by client, according to the FDA 21 CFR 177.1520, to Determine the Total Extractives for the submitted sample - Density - Extractable fraction in n-Hexane - Extractable fraction in Xylene	Pass
006	As specified by client, selected parts of the submitted sample(s) for compliance with American Food and Drug Administration (FDA) 21 CFR 177.1350 (Condition of use E).	Pass
007	Determination of net chloroform soluble fraction according to US FDA 21 CFR 177.1630 - Chloroform-soluble extractives in Distilled water - Chloroform-soluble extractives in 50% Ethyl alcohol - Chloroform-soluble extractives in n-Heptane	Pass
008	As requested by client, according to the FDA 21 CFR 175.300, to determine the total extractives on the submitted sample - Chloroform-soluble extractives in Distilled water - Chloroform-soluble extractives in 8% Alcohol - Chloroform-soluble extractives in n-Heptane	Pass

Test Result:

Sample Description

No.	Sample	Description
001, 002	End Cap, Casing	PP
003	WASHER	TPR
004	FILTER	PP
005	FILTER	PE
006	FILTER	EVA glue
007	Foam	polyester fiber
008	Tablet	EVO-CMASI

1. FDA 21 CFR 177.1520-PP

Method: Solubility in boiling 4.2N HCl - US FDA 21 CFR 177.1520

Maximum extractable fraction in selected solvents - US FDA 21 CFR 177.1520

Test Item(s)	Unit	Result			MDL ($mg//inch^2$)	Limit
		001	002	004		
Melting Point	℃	173	170	175	/	160-180
Density	g/cm^3	0.88	0.89	0.91	/	0.880-0.913 g/cm^3
Extractable fraction in n-hexane	%	4.3	4.6	3.6	0.5	6.4
Soluble fraction in xylene	%	5.6	5.3	4.2	1.0	9.8

Note: g/cm^3 = grams per cubic cementer % = mass percent .

MDL=Method Detection Limit

2. FDA 21 CFR 177.2600 – Total extractives:

Method:To refer to the FDA 21 CFR 177.2600.

Analyte	Condition	Result ($mg/inch^2$)	MDL ($mg/inch^2$)	Limit ($mg/inch^2$)
		003		
Total Extractives in Water	First 7 hours	<3	0.1	≤20
	Succeeding 2 hours	<0.1	0.1	≤1
Total Extractives in N-hexane	First 7 hours	30	0.1	≤175
	Succeeding 2 hours	3.56	0.1	≤4

Note: mg/ $inch^2$ =milligrams per square inch

MDL= Method Detection Limit.

3. FDA 21 CFR 177.1520-PE

Method: Solubility in boiling 4.2N HCl - US FDA 21 CFR 177.1520

Maximum extractable fraction in selected solvents - US FDA 21 CFR 177.1520

Test Item(s)	Unit	Result	MDL ($mg/inch^2$)	Limit
		005		
Density	g/cm^3	0.9	/	0.880-0.913 gm/cm^3
Extractable fraction in n-hexane	%	3.4	0.5	6.4
Soluble fraction in xylene	%	4.1	1.0	9.8

Note: g/cm^3 = grams per cubic cementer % = mass percent .

MDL=Method Detection Limit

4. Test method: (FDA) 21 CFR 177.1350

Test Item(s)	Unit	Testing Condition	MDL (ppm)	Result	Limit (ppm)
				006	
Total nonvolatile extractives (D.I.-Water, 120℉, 24 hours)	mg/in^2	With reference to CFR Title 21, Pt 177.1350 condition E.	-	0.11	0.5
Total nonvolatile extractives (n-Heptane, 70℉, 30 min)	mg/in^2	With reference to CFR Title 21, Pt 177.1350 condition E.	-	0.14	0.5
Total nonvolatile extractives (8%Alcohol, 120℉, 24 hours)	mg/in^2	With reference to CFR Title 21, Pt 177.1350 condition E.	-	0.09	0.5
Total nonvolatile extractives (50% Alcohol, 120℉, 24 hours)	mg/in^2	With reference to CFR Title 21, Pt 177.1350 condition E.	-	0.27	0.5

Note: 0.1wt% = 1000ppm; mg/kg = ppm
MDL=Method Detection Limit
" - " = Not Regulated

5. US FDA 21 CFR 177.1630

Method: Determination of net chloroform soluble fraction according to US FDA 21 CFR 177.1630

Test Item(s)	Unit	Testing Condition	Result	MDL	Limit
			007		
Extractives residue (Water)	$mg/inch^2$	45℃, 24hr	ND	0.1	≤0.5
Extractives residue (8% ethanol)	$mg/inch^2$	45℃, 24hr	ND	0.1	≤0.5
Extractives residue (n-Heptane)	$mg/inch^2$	45℃, 24hr	ND	0.1	≤0.5

Note: MDL=Method Detection Limit ND=Not Detected, less than reporting limit.
$mg/inch^2$=milligram per square inch.

6. FDA total extractinves

Test method : 21 CFR 175.300.

Analyte	Test Condition	Result($mg/inch^2$)	MDL ($mg/inch^2$)	Requirement ($mg/inch^2$)
		008		
Extractives in distilled water	120℉ 24h	ND	1.0	18
Extractives in 8% ethanol	70℉ 0.5h	ND	1.0	18
Extractives in n-Heptane	70℉ 0.5h	ND	1.0	18

Note: $mg/inch^2$ = milligram per square inch
N.D = Not Detected.
MDL=Method Detection Limit

PICTURE OF SAMPLE

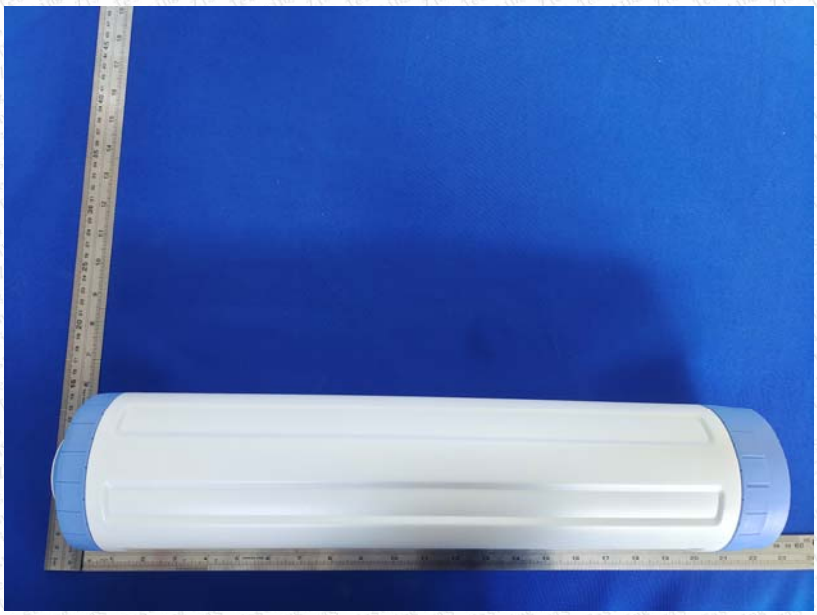

Photo 1

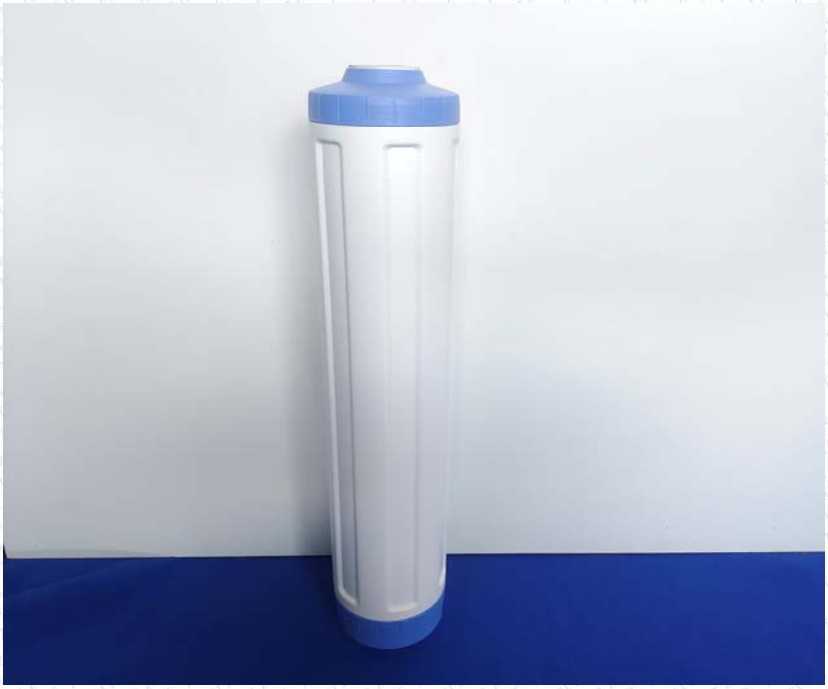

Photo 2

End of Report