

Report of Analysis

Client: Calyx Containers
500 Lincoln Street
Allston, MA 02134

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Attn: Tobe Nightengale

Lab Tracking #: 68115
Report #: 2 of 2
Received On: 03/24/2022
Analysis Dates: 03/28/2022 – 05/02/2022
Report Date: 05/05/2022
P.O. Number: 2694

Sample ID: Calyx 25D Flower Container – CLR
Base: Calyx 25D Base, SKU: 25B-CLR
Lid: Calyx 25D Lid, SKU: 25L-GRN
Lot# 19044

Test Methods: USPNF 2021 Issue 3 General Chapter <671>:
1. Classification Based on Desiccant Method for Solid Oral Dosage Forms – Method 5
2. Moisture Vapor Transmission for Plastic Packaging Systems–Desiccant Method – Method 1

Reference Standards: Not Applicable

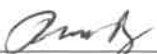
Test Results: See pages 2 – 3

Attachments: Excel Spreadsheet Desiccant Method 1 (2 pages)

Comments: Testing was conducted according to USPNF 2021 Issue 3 requirements. Samples meet the USP/NF classification for tight containers per <671> Method 5. <671> Method 1 testing reported as found and significance of results will be determined by the client.

Laboratory Management Approval,

Quality Assurance Data Review,


Rafael Perez
Analytical Chemistry Manager

Date: 5/5/22


Jessica Alfaro
Supervisor, Quality Assurance

Date: 5/5/22

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TEST RESULTS

USP <671> Classification Based on Desiccant Method – Method 5

Container #	mg/day/liter
1	3
2	3
3	3
4	3
5	3
6	3
7	4
8	4
9	3
10	3

Classification: Packaging systems are classified as “tight” containers if NMT 1 of the 10 test containers exceeds 100 mg/day/L in moisture vapor transmission and none exceeds 200 mg/day/L. Packaging Systems are classified as “well-closed” containers if NMT 1 of the 10 test containers exceeds 2000 mg/day/L in moisture vapor transmission and none exceeds 3000 mg/day/L.

Comment: The packaging system is classified as tight since none of the 10 test containers exceeded 100 mg/day/L in moisture vapor transmission.

TEST RESULTS

USP <671> Moisture Vapor Transmission for Plastic Packaging Systems–Desiccant Method–Method 1

Container #	mg/day
1	2.7371
2	2.8957
3	2.7529
4	2.8943
5	3.1643
6	2.7829
7	2.8686
8	2.7443
9	2.8900
10	2.7771
11	2.8914
12	2.7871
13	2.8800
14	2.8900
15	2.8814
Standard Deviation	0.1058
Avg.	2.8558

Classification: Not Applicable: Report the moisture vapor transmission rate as the average value, in mg/day per container, and the standard deviation of 15 slopes.

***** End of Report *****

USP <671> - MVT Method 1

LTN: 68115

Analyst:

PP

Date:

5/2/2022

Container #	Container Weights (mg) at Timepoint (Days)						Slope (avg mg/day)	Intercept ^B
	0 ^A	7	14	21	28	35		
1	65161.5	65180.2	65199.6	65217.3	65237.2	65257.2	2.7371	65160.8
2	65166.7	65186.0	65206.6	65225.8	65246.5	65267.4	2.8957	65165.7
3	65176.1	65194.3	65214.0	65231.9	65251.9	65271.7	2.7529	65175.0
4	65164.1	65182.6	65203.4	65223.0	65243.8	65263.7	2.8943	65162.5
5	65156.4	65175.1	65199.0	65220.2	65242.7	65264.0	3.1643	65153.8
6	65181.2	65199.9	65219.7	65238.1	65258.3	65278.0	2.7829	65180.4
7	65187.4	65206.7	65226.8	65246.0	65266.8	65287.1	2.8686	65186.4
8	65184.5	65203.3	65222.5	65240.6	65260.2	65280.5	2.7443	65183.8
9	65199.8	65218.7	65239.2	65258.9	65279.7	65299.6	2.8900	65198.5
10	65194.8	65213.7	65232.9	65251.6	65271.7	65291.5	2.7771	65194.0
11	65166.9	65186.2	65206.2	65225.6	65246.8	65267.1	2.8914	65165.7
12	65176.7	65195.6	65215.3	65234.0	65254.0	65273.8	2.7871	65176.0
13	65184.3	65203.8	65223.4	65243.7	65264.2	65284.2	2.8800	65183.4
14	65197.7	65217.3	65237.8	65256.9	65277.9	65298.4	2.8900	65197.0
15	65167.5	65187.2	65207.2	65227.2	65247.9	65267.7	2.8814	65166.9

^A Initial (T₀) weights not used in linear regression.^B Provided for Information Only

Slope Std. Deviation:	0.1058
Avg. Slope (mg/day):	2.8558

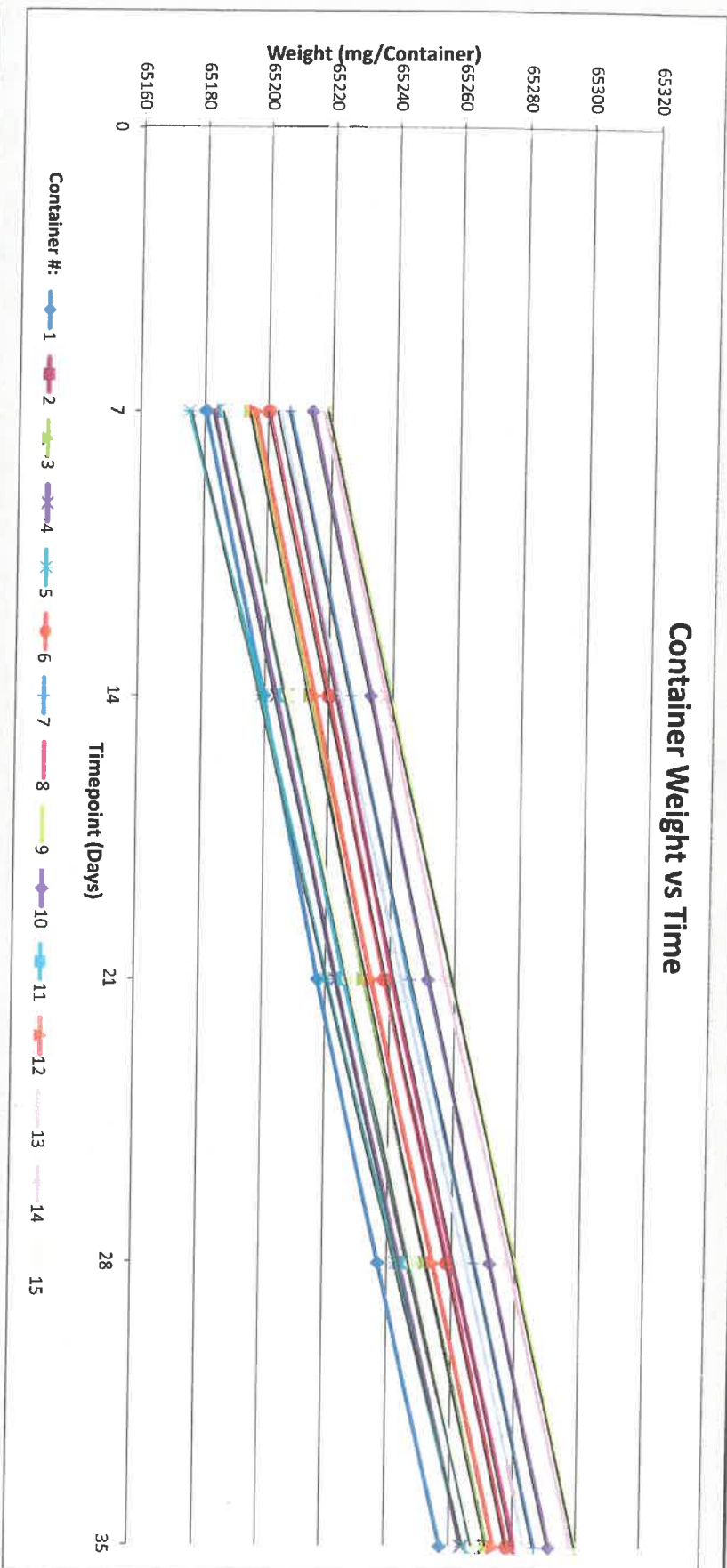
Analyst: PP 5/2/22

Lab Review: AP 5/2/22

QAU: NS 5/4/22

File Path: F:\Excel Templates\Validated Excel Templates\Containers\IVES-0033-R2 MVT Method 1 4 Place.xlsx\Graph

USP <671> - MVT Method 1			
LTN:	68115	Analyst:	PP
		Date:	5/2/2022



Analyst:	PP 5/2/22	Lab Review:	AP 5/2/22	QAU:	NS SL4/22
File Path:	F:\Excel Templates\Validated Excel Templates\Containers\VES-0033-R2 MVT Method 1 4 Place.xlsx\Graph				