MY CO2 (PG) SDN BHD | SAMM No. 384
201701042071 (1256244-P)
MY CO2 (KL) SDN BHD | SAMM No. 564
201501029820 (1155142-M)
MY CO2 (JB) SDN BHD | SAMM No. 752
201501029979 (1155302-A)
MY CO2 CERTIFICATION SDN BHD
201601026813 (1197752-X)
MY CO2 CERTIFICATION PTE LTD
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SUMMARY TEST REPORT

FOR

TEVO CREATIONS SDN. BHD.

NO 2, LORONG BERINGIN 1,

TAMAN INDUSTRI BERINGIN,

14100 SIMPANG AMPAT PULAU PINANG,

MALAYSIA

Type of Product Testing	*BERRY C*
Date of testing	*29 November 2021-30 May 2022*
Stability report issue on	*09/09/22*

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1.0 INTRODUCTION

MY CO2 (PG) Sdn. Bhd. was engaged by Tevo Creations Sdn.Bhd to conduct a lab testing for product **Berry C.** The objective of this testing was to determine the stability profile for storage under accelerated condition.

This report presents a description on the methodology and quality control measures/standard adopted during the laboratory analysis. Finally the results are presented and discussed.

2.0 TEST DESIGN

The product was cloudy colourless solution which packed in a plastic bottle. Then, the product was stored in stability chamber.

Test Material:

Product	Packing Type	Storage Condition/ Period
Berry C	Plastic bottle	40 ± 2°C, 75 ± 5%RH* Accelerated 1 month = Real Time 6 month

* Relative Humidity

Note: Test duration for stability test was based on the Guidelines for Stability Studies/ Testing of Drug Products, National Pharmaceutical Control Bureau, Ministry of Health Malaysia. 1 month accelerated= 6 months of real time.

Testing Plan:

a) Storage Conditions and Testing Interval for product **Berry C:**

Lab Reference No.	Date Received	Date Completion	Storage Condition
			Accelerated Stability **40 ± 2°C, 75 ± 5%RH***
PL2111-C82843	29/11/21	07/12/21	0 Month
PL2202-C93593	28/02/22	07/03/22	3rd Month
PL2205-D05071	30/05/22	04/06/22	6th Month

* Relative Humidity

Note: Test duration for stability test was based on the Guidelines for Stability Studies/ Testing of Drug Products, National Pharmaceutical Control Bureau, Ministry of Health Malaysia. 1 month accelerated= 6 months of real time.

b) Testing Parameter

Physical Test:

- Appearance
- Odor

Chemical Tests:

- Alcohol content
- pH

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3.0 QUALITY CONTROL

In general, the quality control (QC) procedures are:

- All phase of works including equipment, sampling, preservation, physical analysis, chemical analysis, microbiological analysis & reporting were generally performed in accordance to recognized Methodologies and Standards.
- QC procedures including routine analysis of duplicates and method blanks, and inline equipment calibration etc. were performed to ensure repeatability and quality of the results.

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4.0 METHODOLOGY OF ANALYSIS

4.1 Physical Testing

4.1.1 Appearance (Organoleptic)

By physical description.

4.1.2 Odor (Organoleptic)

By sensory testing

4.2 Chemical Testing

4.2.1 pH (APHA 4500-H+B (2005)

Measure the pH of the sample by using the pH meter.

4.2.2 Alcohol content (In house method based on J.Chem.Metrol: 2013)

This method is to measure the concentration of ethyl alcohol by using headspace gas chromatography-flame ionization detection (HS-GC-FID) analysis.

4.2.3 Benzalkonium chloride (titration)

Determination of the anionic active matter in a medium consisting of an aqueous and a chloroform phase by titration with a standard volumetric cationic-active solution (benzethonium chloride) in the presence of an indicator which consists of a mixture of a cationic dye (dimidium bromide) and an anionic dye (acid blue 1).

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5.0 RESULTS

The analysis results are presented in the following table;

Parameters	Specification	Month		
		0 Month (29/11/21)	3rd Month (28/02/22)	6th Month (29/05/22)
Appearance*	NA	Cloudy colourless solution	Cloudy colourless solution	Cloudy colourless solution
Odor*	NA	Characteristic odor	Characteristic odor	Characteristic odor
pH	NA	6.1	6.0	6.0
Alcohol content (ppm)	NA	ND < 0.1	ND < 0.1	ND < 0.1
Benzalkonium chloride* (% w/v)	NA	0.17	0.24	0.33

i) * indicate not SAMM accredited.

ii) NA indicate not applicable due to no specification provided/refer to.

iii) ND indicate not detected

Physical stability

The physical stability of sample proved to be unchanged after 6th months of storage under accelerated conditions at 40 ± 2°C, 75 ± 5% RH

Chemical stability

Based on the chemical stability result, pH of the product has some variations while for benzalkanium chloride showing increasing from 0 month till 6th month of accelerated conditions. No alcohol content was detected during the 6 month of accelerated conditions.

6.0 CONCLUSION

Based on the tabulated results as shown above, this product is an alcohol free product.

7.0 REFERENCES:

1) Drug registration guidance document (DRGD), third edition, July 2022

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