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TEST REPORT CERTIFICATE

Reference Number	DBCP/GI/01-19
Sample Name	Diabliss Sugar Normal Cane Sugar
Details of Samples	Diabliss Sugar - Consumer Pack, 500gx4 packets Normal Cane Sugar - 2 kg
Sample processed by	Dr. Varun, MBBS
Date Received	December 15, 2018
Date of Testing	January 17-25, 2019
Title of Study	Glycemic Index of Diabliss Sugar and Untreated Cane Sugar
SUMMARY CONCLUSIONS: EFFICACY RESULTS: Diabliss Sugar has low glycemic index. Untreated Cane Sugar has medium glycemic index. SAFETY RESULTS: There are no observed adverse effects. CONCLUSION: The GI value of Diabliss Sugar is 46.5 and classified under low glycemic food/nutrient. The GI value of Untreated Cane Sugar is 62.8 and classified under medium glycemic food/nutrient.	

Primary Investigator:



Dr. A. Franklin, MSc, PhD
Associate Dean & Professor of Microbiology
Anna Medical College, Mauritius

1/2/19

Date

Reference Number: DBCP/GI/01-19

CONFIDENTIAL

Glycemic Index Study Report

Glycemic Index of Diabliss Sugar & Untreated Cane Sugar

DBCP/GI/01-19

Report submission date: February 1, 2019

TEST Report

Sponsor

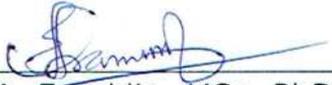
DiaBliss Consumer Products Pvt Ltd
Type II/20, Dr.VSI Estate,
Thiruvanmiyur, Chennai - 600041
Tamilnadu, India

Reference Number: DBCP/GI/01-19

Signature Page for the Study Report

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study

Primary Investigator:



Dr. A. Franklin, MSc, PhD
Associate Dean & Professor of Microbiology
Anna Medical College, Mauritius

1/2/19

Date

Research Associate:



Dr. R. Varun, MBBS

01/02/19

Date

Reference Number: DBCP/GI/01-19

1. TITLE PAGE

Study Title: Glycemic Index of Diabliss Sugar and Untreated Cane Sugar

Indication studied: Glycemic Index evaluation on healthy volunteers

Sponsors: Diabliss Consumer Products Pvt Ltd

Type II/20, Dr.VSI Estate,
Thiruvanmiyur, Chennai - 600041, Tamilnadu, India

Protocol:

The protocol used was in line with procedures recommended by the Food and Agriculture Organization/World Health Organization (1998)¹. Ten subjects were recruited to determine GI of Diabliss Sugar and Untreated Cane Sugar. On the day prior to the test subjects were asked to restrict their activities and were asked not to eat or drink after 20:00 hours the night before OGTT, although moderate quantities of water were allowed.

Principal Investigator: Dr. A. Franklin, MSc, PhD

Date of report: February 1, 2019

2. SYNOPSIS

Name of Sponsor: Diabliss Consumer Products Pvt Ltd	Individual Study Table Referring To Module 5 of The CTD: N/A Volume: N/A Page: N/A		(For National Authority Use Only) N/A
Name of Active Ingredient(S) : N/A			
Title of Study	Glycemic Index of Diabliss Sugar and Untreated Cane Sugar		
Investigator(s)	Dr. A Franklin, MSc, PhD		
Publication	N/A		
Study period	January 17-25, 2019	Phase of development: Commercial Samples	Phase : N/A
Objectives	To determine the glycemic response of Diabliss Sugar and Untreated Cane Sugar		
Methodology	50 grams of a standard food, dextrose, 50.2 grams of Diabliss Sugar containing 99.7% total carbohydrate content or 50 grams of carbohydrate equivalent (test food 1), 50.1 grams of Untreated Cane Sugar from the same batch of sugar used to manufacture Diabliss Sugar (test food 2) were used in the study. OGTT was performed in the morning after 12 hours of overnight fasting. After collecting blood sample to determine fasting blood glucose on three separate days, dextrose or test foods was administered orally with adequate quantities of water. Blood samples were collected every 15 minutes in the first hour and every 30 minutes in the second hour. Blood glucose concentration was determined by capillary method. Glucose OGTT was administered on two separate days, followed by Diabliss Sugar and Cane Sugar OGTT tests. Each test was conducted two days apart.		
Number of volunteers	10		
Diagnosis and main criteria for inclusion	Ten healthy subjects were recruited. Subjects were moderately active, non-smokers and non-alcoholics. Exclusion criteria were as follows: Age <18 yrs or > 55 yrs, HbA1c Values <6.0%.		

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Test product, dose & mode of administration	Diabliss Sugar, 50.2g containing 99.7% total carbohydrate content (50 grams of carbohydrate equivalent), 50.1g of Untreated Cane Sugar containing 99.9% carbohydrate were administered through oral route of administration
Criteria for evaluation	The area under the curve has been calculated as the incremental area under the blood glucose response curve (iAUC), ignoring the area beneath the fasting concentration. This can be calculated geometrically by applying the trapezoid rule. When a blood glucose value falls below the baseline, only the area above the fasting level is included.

SUMMARY CONCLUSIONS

EFFICACY RESULTS: DiaBliss Sugar has low glycemic index. Untreated Cane Sugar has medium glycemic index.

SAFETY RESULTS: There are no observed adverse effects.

CONCLUSION: The GI value of Diabliss Sugar is 46.5 and classified under low glycemic food/nutrient. The GI value of Untreated Cane Sugar is 62.8 and classified under medium glycemic food/nutrient.

DATE OF THE REPORT: February 1, 2019

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4. LIST OF ABBREVIATIONS & DEFINITION OF TERMS

AE	:	Adverse Event
FAO	:	Food and Agriculture Organization
GI	:	Glycemic Index
IAUC	:	Incremental area under the curve
ISO	:	International Standards of Organization
N/A	:	Not Available
OGTT	:	Oral Glucose Tolerance Test
WHO	:	World Health Organization

5. SUBJECT INFORMATION AND CONSENT

All subjects were provided written informed consent to participate in the study prior to being screened. The subject information sheet detailed the procedures involved in the study (aims, methodology, potential risks, anticipated benefits) and the investigator explained these to each subject. The subject signed the consent form to indicate that the information had been explained and understood. The subject was then allowed time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The subject was given a copy of the informed consent form for their information. The original copy of the informed consent was kept in a confidential file in the Investigators centre records.

6. INTRODUCTION

6.1 BACKGROUND:

Diet modification plays an important role in the management of type 2 diabetes. The glycemic index (GI) was proposed in the 1980s to classify carbohydrates and various foods based on their impact on postprandial blood glucose levels.

Research suggests that there are clinically useful benefits of using low glycemic index (GI) diets in the management of diabetes. Identifying ingredients that decrease post-prandial glucose levels may be beneficial for developing low glycemic foods and supplements. Clinical studies have also shown that low GI foods to deliver benefits with respect to Lower blood glucose levels, Lower lipid levels, Improved weight management and Lower risk of cardiovascular disease. This study compares the glycemic impact of Diabliss Sugar versus Untreated cane sugar from the same batch used in Diabliss Sugar manufacture.

7. STUDY OBJECTIVE

To evaluate the Glycemic Index of Diabliss Sugar. A secondary objective of the study was to compare the GI of Diabliss Sugar vis a vis untreated cane sugar made from the same batch as the herbal extract fortified Diabliss Sugar

8. INVESTIGATIONAL PLAN

Ten non-blind, repeated measure, crossover design trials were undertaken in a groups of healthy subjects. All the subjects satisfied the inclusion criteria. The following summarizes their values:

Reference Number: DBCP/GI/01-19

Subject No	Male /Female	Age	Height	Weight, kg	BMI	HbA1c
1	Female	49	5'	69	29.7	5.8
2	Female	29	5'	46	19.8	5.5
3	Female	28	5' 6"	54	19.2	5.6
4	Female	26	5' 8"	56	18.2	5.5
5	Male	22	5' 7"	64	22.1	5.4
6	Male	30	5' 11"	80	24.6	5.7
7	Male	30	5' 11"	105	32.3	5.6
8	Male	24	6'	115	34.4	5.4
9	Female	27	5' 3"	65	25.4	5.5
10	Male	26	5' 9"	72	23.4	5.6
	Average	29.1		72.6	24.9	5.6
	St Dev	7.4		22.1	5.6	0.1

Each trial was conducted at random and on separate days. A gap of two days was given between each test. GI testing with 10 subjects was conducted according to the FAO/World Health Organization (WHO) guidelines. The study was used dextrose as the standard food. Subjects were also required to fast for 10 hours prior to their study visit.

8.1 INCLUSION CRITERIA

Participants who were aged below 18 years or above 55 years, and those with Glycated Hemoglobin (HbA1c) levels of < 6.0% were included in the study.

8.2 EXCLUSION CRITERIA

Subjects with HbA1c (Glycated Hemoglobin) levels of > 6.0, Diabetics, those with cardio vascular disease, hypertension, pregnant women, and subjects who recently underwent surgeries were excluded from the study.

8.3 DESCRIPTION OF INVESTIGATIONAL PRODUCTS

OGTT was performed in the morning after 12 hours of overnight fasting at 8 am on each test occasion. 50 grams of the standard food (Dextrose, Reagent grade anhydrous dextrose, 99.999%) and 50.2 grams of Diabliss Sugar containing 99.7% total carbohydrate content (test food 1), 50.1 grams of Untreated Cane Sugar containing 99.9% total carbohydrate content (test food 2) or 50g of total carbohydrate intake was administered to each subject in the study. Each of the food

was dissolved in 200 ml of water and administered instantly to each subject. After consuming the test food or standard food, each subject was allowed to consume up to 200 ml of water. Blood samples were collected every 15 minutes in the first hour and every 30 minutes in the second hour. Blood glucose concentration was determined by capillary method. Capillary test strips used were from less than 3 months of date of manufacture. The strips selected were wrapped in aluminized foil by the manufacturer to ensure no moisture/environmental degradation. The standard food test was repeated two times, followed by test foods. A minimum of two days was given between each test.

8.4 STATISTICAL ANALYSIS

For each test, the incremental area under the curve was calculated according to the Trapezoidal method. Any area under the baseline (fasting value for the test food) was ignored. Results represented as means. GI of test food is expressed as mean for the whole group.

9. RESULTS AND INFERENCE:

The GI value of Diabliss Sugar tested in the present study was found to be 46.5 (Table 1, Figure 1). Therefore, Diabliss Sugar is classified as a low GI food.

The GI value of Untreated Cane Sugar tested in the present study was found to be 62.8 (Table 2, Figure 2). Therefore, Cane Sugar is classified as a medium GI food.

As per the Food and Agriculture Organization GI cut-off values are as follows²: Low <55; Medium 56-69 inclusive; High >70

Figure 1: Average Oral Glucose Tolerance Test (Glucose & Diabliss Sugar)

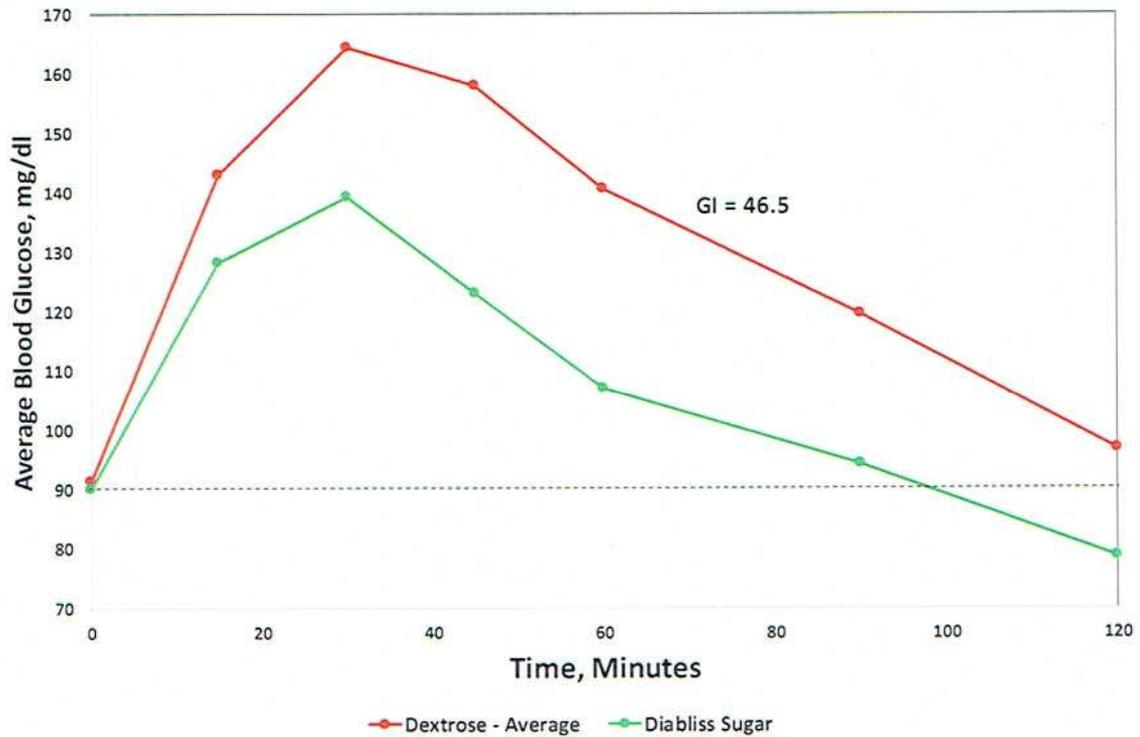


TABLE -2: Average & Standard Deviation of Blood Sugar of ten subjects: (Glucose and Untreated Cane Sugar)

Data Summary: Average Blood Glucose Values				
Time, min	Dextrose - Average	Untreated Cane Sugar	St Dev, Dextrose - Average	St Dev, Untreated Cane Sugar
0	91	88	11	3
15	143	137	17	8
30	164	151	26	11
45	158	136	37	16
60	141	116	34	22
90	120	91	24	12
120	97	80	28	8
GI Calculation: Incremental Area under curve (iAUC) Method				
AUC 0-15	386.1	369.0		
AUC 15-30	932.8	842.3		
AUC 30-45	1045.5	828.8		
AUC 45-60	867.4	564.8		
AUC 60-90	1159.5	460.5		
AUC 90-120	503.3	10.4		
Total AUC	4894.5	3075.7		
NOTE: Area below fasting level of 88 mg/dl ignored				
GI	62.8			

Figure 2: Average Oral Glucose Tolerance Test (Glucose & Untreated Cane Sugar)

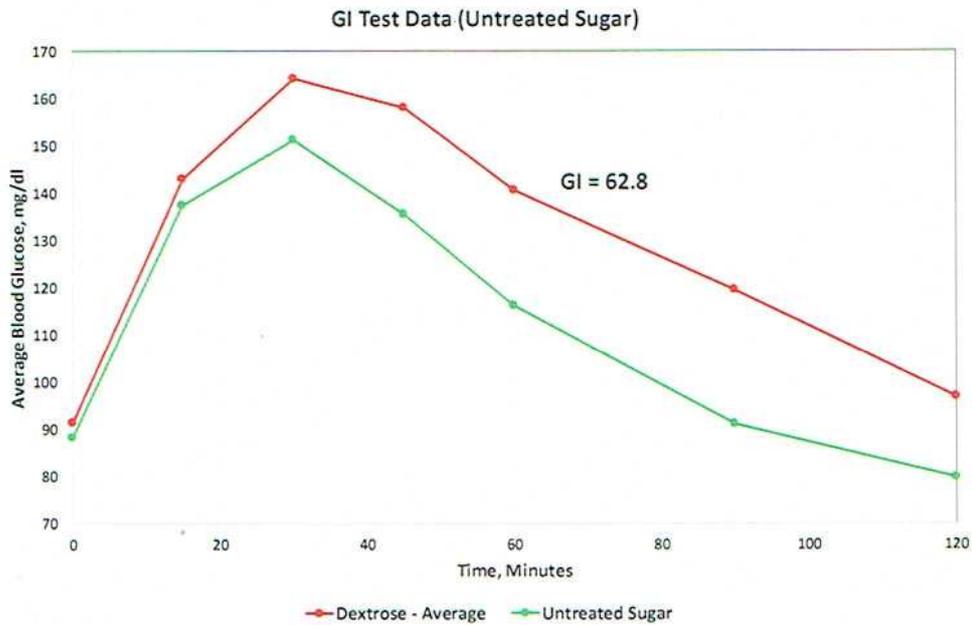
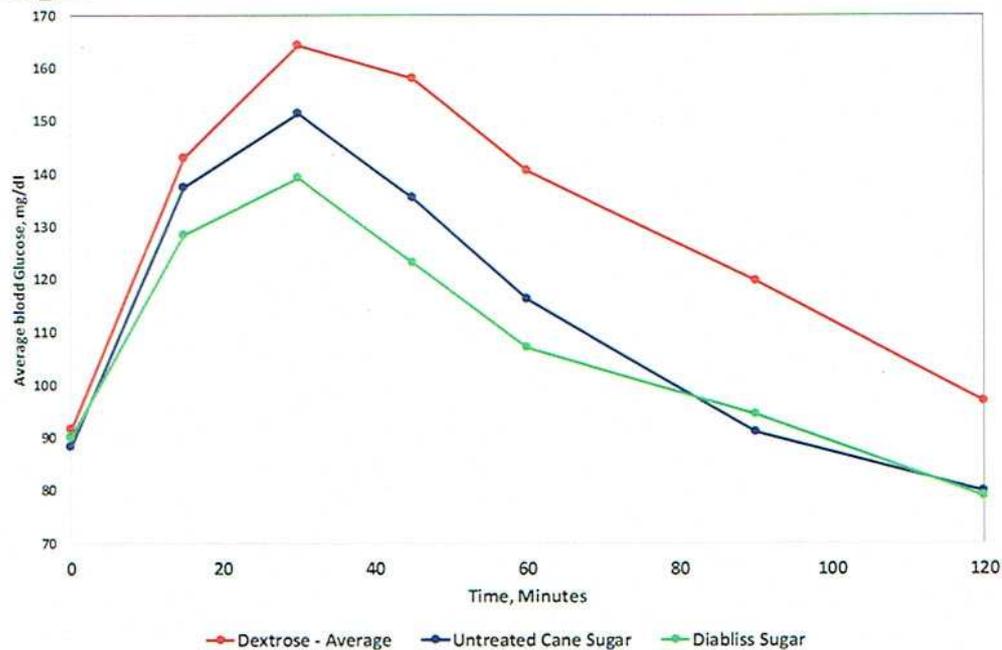


Fig 3: OGTT comparison between Diabliss Sugar and Cane Sugar



11. REFERENCES

1. Food and Agriculture Organization of United Nations, Carbohydrates in human nutrition (FAO Food and Nutrition Paper — 66, Chapter 4 - The role of the glycemic index in food choice. [http://www.fao.org/docrep/w8079e/w8079e0a.htm#definition of glycemic index \(GI\)](http://www.fao.org/docrep/w8079e/w8079e0a.htm#definition%20of%20glycemic%20index%20(GI))
2. International Organization for Standardization in: ISO 26642:2010 "Food products - Determination of the glycaemic index (GI) and recommendation for food classification".
3. Jenkins DJ, Wolever TM, Taylor RH, Barker H, Fielden H, Baldwin JM, Bowling AC, Newman HC, Jenkins AL, Goff DV. Glycemic index of foods: a physiological basis for carbohydrate exchange. *Am J Clin Nutr* 1981;34:362-6.
4. Fiona S. Atkinson, RD, Kaye Foster-Powell, RD and Jennie C. Brand-Miller, PHD, International Tables of Glycemic Index and Glycemic Load Values: 2008, *Diabetes Care*, volume 31, number 12, December, 2008
5. J Mann, JH Cummings, HN Englyst, T Key, S Liu, G Riccardi, C Summerbell, R Uauy, RM van Dam, B Venn, HH Vorster and M Wiseman; FAO/WHO Scientific Update on carbohydrates in human nutrition: conclusions; *European Journal of Clinical Nutrition* (2007) 61 (Suppl 1), S132–S137;