



Ref No: BVDU/IRSHA/

Date: 3/12/2021

DRAFT REPORT

Study Title: Virucidal activity assessment of products against SARSCoV-2 Virus

Testing laboratory Name	National Immunogenicity and Biologics Evaluation Centre (NIBEC), IRSHA, BVDU
IRSHA Study Number	SCoAV-31
Customer Name and Address	Sundar Dezire Pvt Limited, 6G Century Plaza 560-562, Anna Salai, Teynampet, Chennai 600018
Client project number	Not Applicable
Task order number	02
Date of Sample Receipt	4 th October 2021
Start date of Testing	24 th November 2021
End date of Testing	29 th November 2021
Date of Draft reporting	3 rd December 2021
Date of Final reporting	
Specimen Used for testing	Korona Guard Candy Batch Number:C210925
Testing Condition	Antiviral testing 1. Evaluation of the virucidal activity of the test products against SARS-CoV2 virus at recommended contact time and concentration.

Dr. Sudha Ramkumar
Authorized Signatory

The test results in this report refer only to the batch of items supplied by the customer for testing. The results provided may be submitted to regulatory authorities as scientific proof. The results must not be used for claims that are unsubstantiated by regulatory authorities. All reports are archived at NIBEC, IRSHA for a maximum period of 1 years. The sample will be retained for 3 months after submission of final report unless otherwise requested in writing.



Scope:

The estimation of the virucidal activity exhibited by test products that are either ready to use or form a homogeneous physically stable preparation when diluted with distilled water against SARS-CoV2 virus.

Test Virus Summary:

Realm	Riboviria
Order	Nidovirales
Family	Coronaviridae
Genus	Betacoronavirus
Species	SARS-CoV-2 (COVID-19 virus)
NCBI Accession number	MT416726

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Test Information Summary

Identification of the sample	
Name of the product	Korona Guard Candy
Manufacturing details provided by Client	C210925
Date of Manufacturing as provided by Client	Not Mentioned
Product Diluent Recommended	Distilled water
Product Appearance	Colourless liquid
Active Substance(s) and concentration(s)	Polyoxyl 40 Hydrogenated Castor Oil (As castor oil derivative) Each 6 gm contains 37 mg active component
Manufacturer/Supplier	Sundar Dezire Pvt Ltd
Specimen storage condition	Ambient
Experimental Condition	
Contact time	30 min
Test Temperatures	37 °C
Interfering substance	Clean condition: 0.3gm/L BSA
Stability and appearance of the mixture during procedure	No precipitation /flocculation observed
Temperature of incubation for quantal assay	37 °C at 5% CO ₂
Virus used for testing and passage	SARS-CoV-2 (COVID 19 virus) P8
Procedure to stop action of product	Ice cold Minimal Essential Media with 2 % FBS.
Host Cell line used for testing and passage	Vero cell line CCL-81 P 160
Medium of Cell culture	Minimal Essential Media with 2 % Fetal Bovine Serum



Test Result Summary

Product	Concentration	Interfering Substance	Test Temperature	Level of Cytotoxicity	Log TCID after contact time of 1min	Log reduction in comparison to virus control ⁺
Korona Guard Candy (C210925)	Neat	0.3g/L BSA	37°C	1.5 ⁺	3.8	1.7
SARS-CoV2 Virus	Undiluted virus titer: 10 ^{6.5} TCID ₅₀ /ml	0.3g/L BSA	37°C	NA	5.5	

NA: Not Applicable

⁺: Sample passed through Microspin™ S 400 HR columns



Raw Data

Raw data for antiviral assay											
Product	Concentration	Contact time and temperature	Dilutions								
			-2	-3	-4	-5	-6	-7	-8	-9	-10
Korona Guard Candy (C210925)	Neat	30 min at 37°C	3	4	0	0	0	0	0	0	0
			3	4	4	0	0	0	0	0	0
			3	4	0	0	0	0	0	0	0
			3	4	0	0	0	0	0	0	0
Virus Control	Undiluted virus titre 10 ^{6.5} TCID ₅₀ /ml	30 min at 37°C	3	4	4	4	0	0	0	0	0
			3	4	4	4	0	0	0	0	0
			3	4	4	4	0	0	0	0	0
			3	4	4	4	0	0	0	0	0
Raw data for Cytotoxicity ⁺											
Product	Concentration	Contact time and temperature	Dilutions								
			-2	-3	-4	-5	-6	-7	-8	-9	-10
Korona Guard Candy (C210925)	Neat	NA	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0

For Assay plates containing virus: 0 to 4 represents degree of CPE observed due to SARS-CoV-2 virus infection.

(4: all the cells in the well got infected with the virus and showed complete CPE; 0: all the cells in the well remained uninfected and did not show CPE.)

For Assay plates containing only test products without virus (cytotoxicity assay): 0 to 4 represents degree of CPE observed due to cytotoxic nature of test product.

(4: the test product is highly cytotoxic and showed complete CPE; 0: the test product is non cytotoxic and did not show CPE.)



Conclusion

- **Korona Guard Candy** shows **1.7 log reduction (98.04 %)** at undiluted (ready to use) concentration when tested at 37 °C for 30 minute contact time under clean conditions (0.3g/1 Bovine Serum Albumin) against SARS-CoV2/ virus.

End of Report
