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Date: 18/9/2021

**DRAFT REPORT**

**Study Title: Testing of TCG-CREST (RISE) Antiviral cream formulation for efficacy against Covid-19**

Testing laboratory Name:	National Immunogenicity and Biologics Evaluation Centre (NIBEC), IRSHA, BVDU
IRSHA Study Number	SCoAV-12
Customer Name and Address	TCG Centre for Research and Education in Science and Technology 4 <sup>th</sup> Floor, 9B Wood Street, Kolkata 700016, West Bengal, India
Client project number	56780TCG-CREST (RISE)
Date of Sample Receipt	10 <sup>th</sup> August 2021
Start date of Testing	18 <sup>th</sup> August 2021
End date of Testing	24 <sup>th</sup> August 2021
Date of Draft Reporting	18 <sup>th</sup> September 2021
Date of Final Reporting	
Specimen Used for testing	TCG-CREST (RISE) Antiviral cream formulation
Testing Condition	Antiviral testing at 24 hours contact time

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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 standard describes the method for measuring antiviral activity on plastics and other non-porous surfaces of antiviral-treated products against specified viruses.

## Outline of Test Method

A test suspension of the SARS-CoV-2 virus was inoculated on the antiviral cream coated glass panel and its respective control glass panel surface followed by covering with a cover film. The surfaces loaded with virus inoculum were maintained at specified temperature ( $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ) for a contact period of **24** hours maintaining required humidity. At the end of the contact time remaining infectious virus particles were recovered individually from antiviral cream coated glass panel coated panel and its respective control glass panel by washing the surfaces with medium. Quantification of recovered surviving organisms (infectious virus particles) was done by plaque assay. As prescribed in guideline assay was performed in triplicate using 3 test specimen for each step.

## Test Virus Summary

<b>Realm</b>	Riboviria
<b>Order</b>	Nidovirales
<b>Family</b>	Coronaviridae
<b>Genus</b>	Betacoronavirus
<b>Species</b>	COVID-19
<b>NCBI Accession number for virus isolate</b>	MT416726



### Test Information Summary

<b>Guideline referred</b>	ISO 21702 (Measurement of antiviral activity on plastics and other non-porous surfaces)
<b>Details of the specimen</b>	TCG-CREST (RISE) Antiviral cream formulation coated to glass panel and control panel of size 50 mm X 22 mm (treated and untreated) of thickness 2 mm.
<b>Specimen storage condition</b>	Ambient
<b>Type of polymer used for the cover film</b>	Glass cover slip of size 20 mm X 22 mm X 0.1 mm
<b>Virus used for testing</b>	COVID 19 (SARS-CoV-2) P8
<b>Host Cell line used for testing</b>	Vero cell line P163
<b>Volume of test inoculum used</b>	200 µl (1.65 X10 <sup>6</sup> PFU/ml)
<b>Test Concentrations</b>	As supplied
<b>Test Temperature</b>	25 °C ± 1 °C
<b>Temperature of incubation in plaque assay</b>	37 °C
<b>Contact time</b>	24 hours
<b>Stability and appearance of the specimen during the test</b>	No change observed
<b>Neutralizer used</b>	Ice cold SCDLP media

### Test Result Summary

TCG-CREST (RISE) Antiviral cream formulation coated to glass panel has exhibited **2.46 PFU/cm<sup>2</sup>** log reduction corresponding to **99.65 %** reduction (resistance to growth) against COVID 19 virus after **24 hours** of contact time.



**Data Summary**

	Number of plaques recovered						Infectivity titer of virus recovered per cm <sup>2</sup> of test specimen (N)*	Average of the common logarithm of the number of plaques recovered		Antiviral activity per cm <sup>2</sup> (R)**
	Specimen 1		Specimen 2		Specimen 3			U <sub>t</sub>	2.72	
<b>Untreated<sup>A</sup></b>	65	58	56	57	55	58	528.8	U <sub>t</sub>	2.72	<b>2.46</b>
<b>Treated<sup>A</sup></b>	1	0	0	0	0	0	1.8	A <sub>t</sub>	0.26	
<b>Control<sup>B</sup></b>	4	4	2	4	2	2	2727.3	U <sub>0</sub>	3.44	

<sup>A</sup> Dilution Factor: 100; <sup>B</sup> Dilution Factor: 10000

\***Infectivity titer of virus recovered per cm<sup>2</sup>**

$$N = (10 \times C \times D \times V) / A$$

- N* is the infectivity titer of virus recovered per cm<sup>2</sup> of test specimen
- C* is the average number of plaque counted for the duplicate wells
- D* is the dilution factor for the wells counted
- V* is the volume of the neutralizer media added to the specimen, in ml
- A* is the surface area of the cover film, in cm<sup>2</sup>.

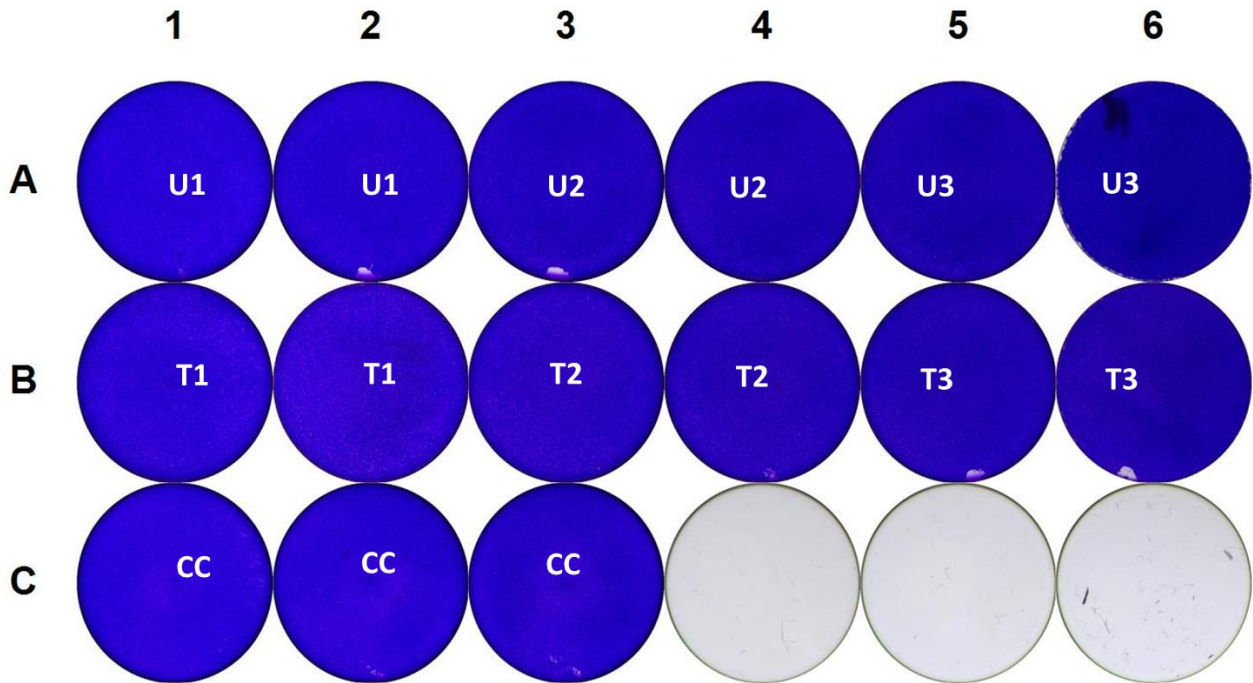
\*\***Antiviral activity (PFU/cm<sup>2</sup>)**

$$R = (U_t - U_0) - (A_t - U_0) = U_t - A_t$$

- R* is the antiviral activity;
- U<sub>0</sub>* is the average of the common logarithm of the number of plaques recovered from the three untreated test specimens immediately after inoculation, in PFU/cm<sup>2</sup>;
- U<sub>t</sub>* is the average of the common logarithm of the number of plaques recovered from the three untreated test specimens after 24 h, in PFU/cm<sup>2</sup>
- A<sub>t</sub>* is the average of the common logarithm of the number of plaques recovered from the three treated test specimens after 24 h, in PFU/cm<sup>2</sup>.

The value of the antiviral activity (*R*) can be used to characterize the effectiveness of an antiviral agent.

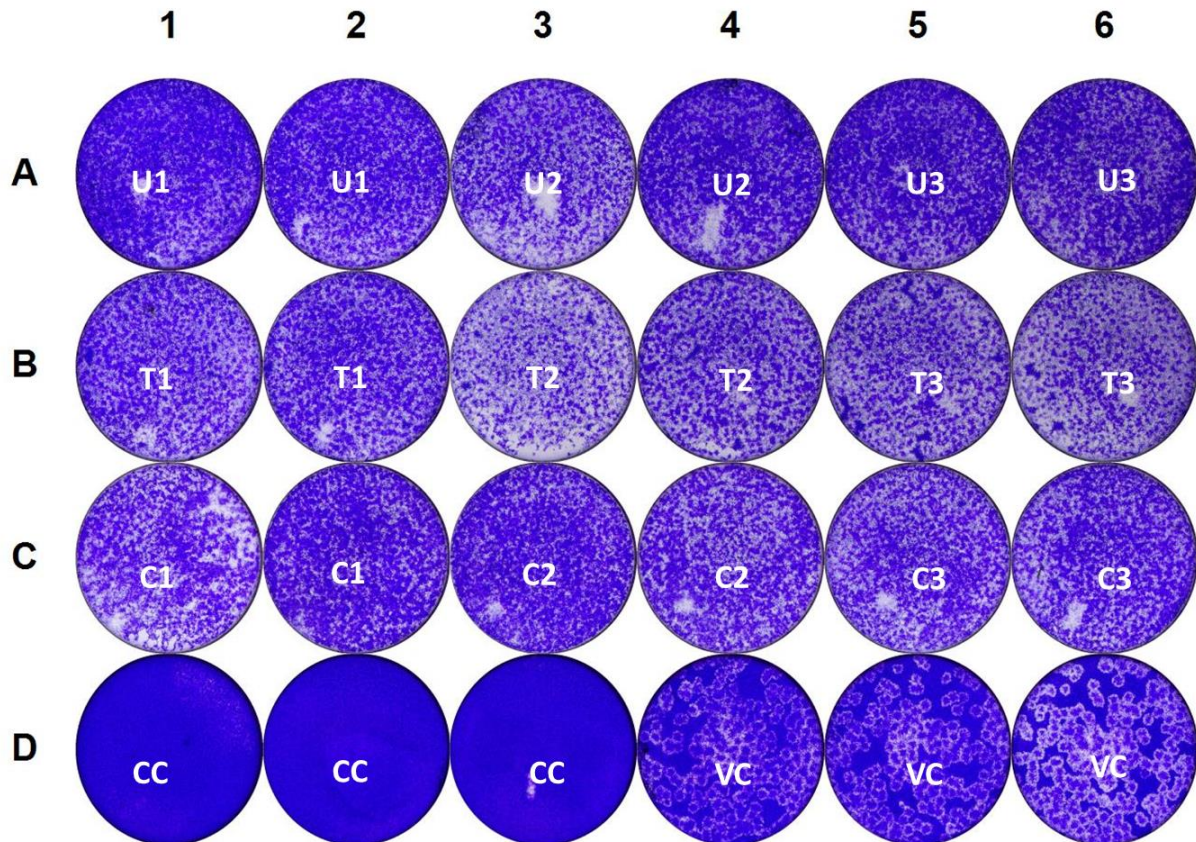
## Representative Images



**Plate 1: Cytotoxicity assessment of TCG-CREST (RISE) Antiviral cream formulation coated to glass panel and its respective control glass panel**

- This image specifies that the test (T) control specimen (UT) is non-toxic on Vero cell line as cell monolayer is observed intact.

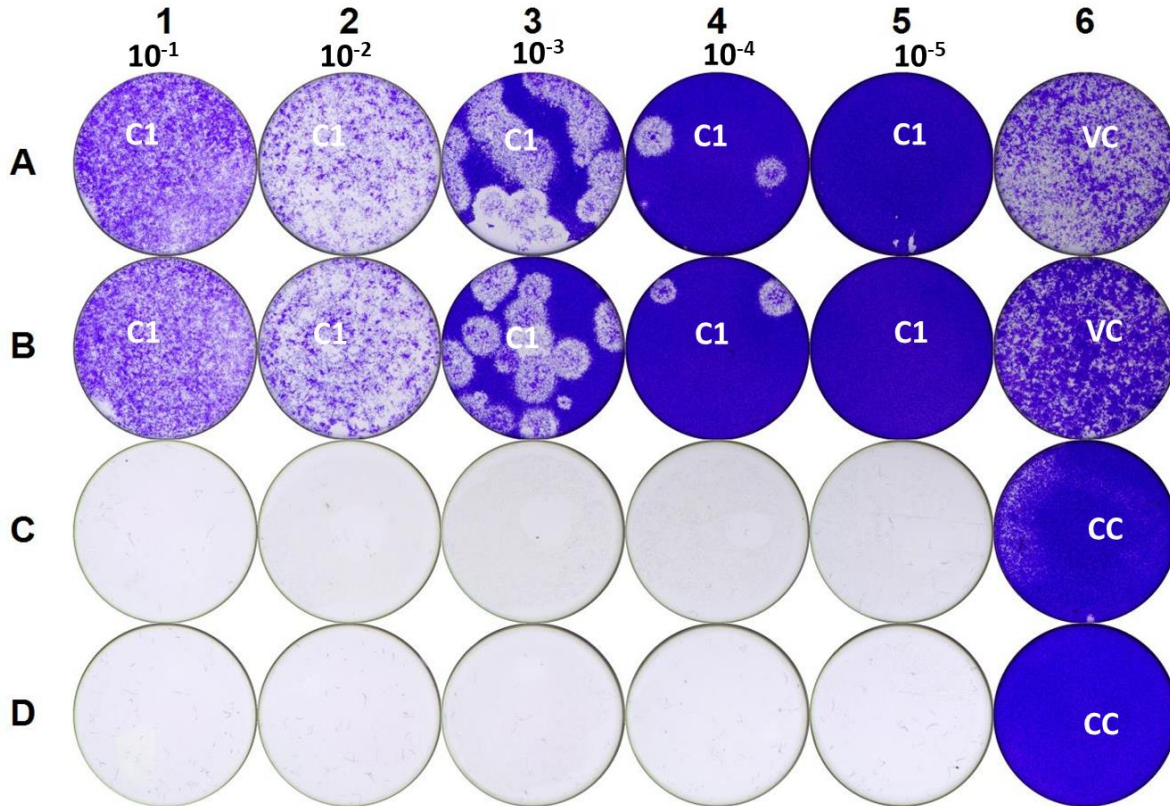
UT: Untreated specimen (control glass panel); T: Treated specimen (TCG-CREST (RISE) Antiviral cream formulation coated glass panel); CC: Cell control.



**Plate 2: Verification of cell sensitivity to virus and the inactivation of antiviral activity**

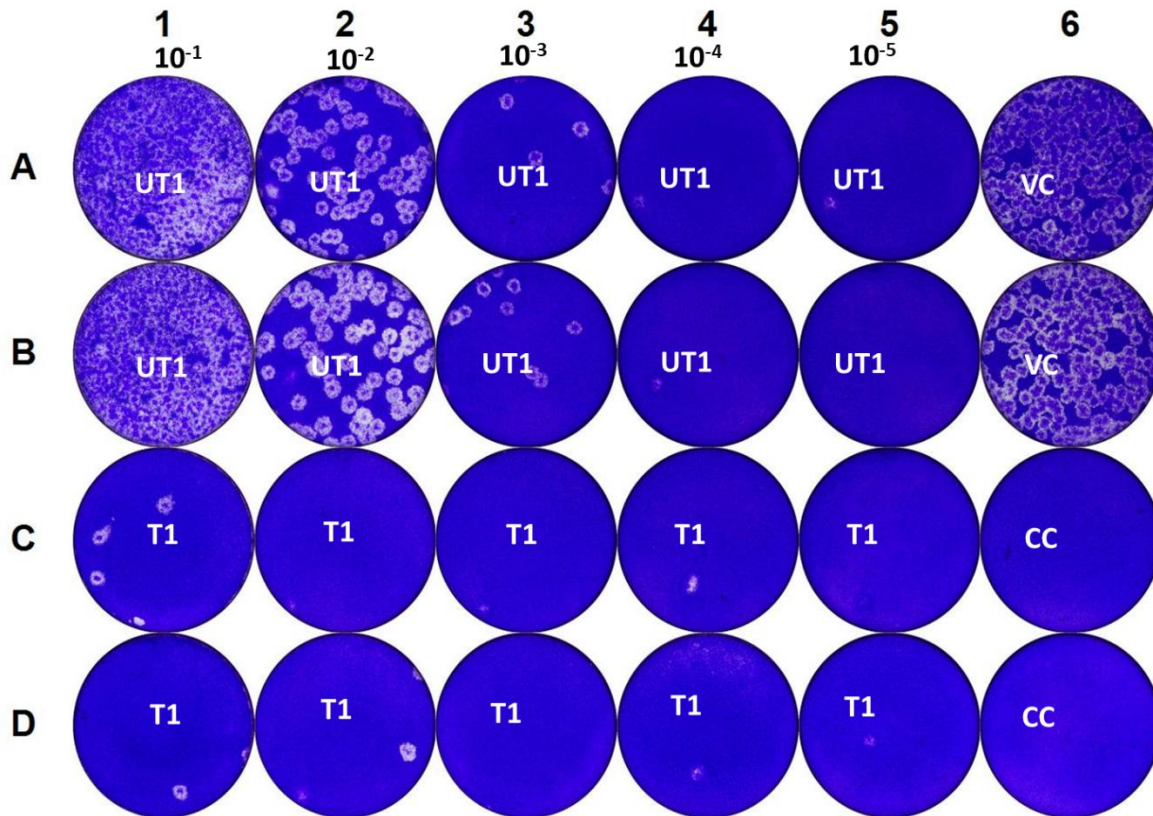
- The purpose of the control test is to confirm the suppressive efficiency of wash media on the test specimen
- This image indicates, the wash media is not cytotoxic and has no effect on the cell sensitivity to the SARS-CoV2 virus infection and virus inactivation as represented by plaques in 'T' 'UT' and 'C' (no specimen) wells.

**UT:** Untreated specimen (control glass panel) washed with medium and spiked with the SARS-CoV-2 virus; **T:** Treated specimen (TCG-CREST (RISE) Antiviral cream formulation coated glass panel ) washed with medium and spiked with the SARS-CoV-2 virus; **C:** Verification of cell sensitivity control (control: medium + virus without treated or untreated specimen); **CC:** Cell control.



**Plate 3: Titration of SARS-CoV2 virus on untreated specimens after immediate wash with the wash media. ( $U_0$  is calculated from this data)**

**UT:** Untreated specimen (control glass panel); **CC:** Cell control; **VC:** Virus control.



**Plate 4: Antiviral assessment of Treated specimen (TCG-CREST (RISE) Antiviral cream formulation coated to glass panel) and Untreated specimen (control glass panel) after 24 hours contact time.**

- The image specifies that, in comparison to UT1 specimen, the T1 shows reduction in the plaque count.
- The image indicates that TCG-CREST (RISE) Antiviral cream formulation coated to glass panel) exhibited virucidal activity against SARS-CoV2 virus. In comparison to untreated control, the retained number of live infectious SARS-CoV-2 virus particles quantified in form of plaques were less in TCG-CREST (RISE) Antiviral cream formulation coated to glass panel than that of respective untreated specimen after contact time of 24 hours.

**UT1:** Untreated specimen (control glass panel); **T1:** Treated specimen (TCG-CREST (RISE) Antiviral cream formulation coated to glass panel); **CC:** Cell control; **VC:** Virus control.

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