STUDY REPORT

STUDY TITLE

SURFACE DISINFECTION BY EXPOSURE TO GERMICIDAL UV LIGHT (UVRova ST)

SPONSOR

SRUJANA ROBOTICS
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STUDY FACILITY

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SIGNATURE APPROVAL PAGE
(REVIN LABS PRIVATE LIMITED)

The study Report for the Report no. "RLPL/016/AMV/R/20/002" entitled "SURFACE DISINFECTION BY EXPOSURE TO GERMICIDAL UV LIGHT (UVRova ST)" has been checked and approved.

The information and data presented in this report is considered as confidential and proprietary information of M/s. SRUJANA ROBOTICS, and will not be disclosed to anyone without the expressed or written approval of sponsor.

Prepared By:

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18/03/2020
.....
(signature & Date)

Reviewed By

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CLIENT APPROVAL SIGNATURE PAGE

(M/s. SRUJANA ROBOTICS)

The study Report for the Report no. "RLPL/016/AMV/R/20/002" entitled "SURFACE DISINFECTION BY EXPOSURE TO GERMICIDAL UV LIGHT (UVRova ST)" has been checked and approved

Approved By:

Mr. YVS JAGANNATH
Technical Head
M/s. SRUJANA ROBOTICS
Hyderabad, TS INDIA

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(signature & Date) 19 Mar 2020

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1. STUDY DETAILS

1.1. Study Title	: SURFACE DISINFECTION BY EXPOSURE TO GERMICIDAL UV LIGHT (UVRova ST)
1.2. Report Number	: RLPL/016/AMV/R/20/002
1.3. Sponsor Details	: **SRUJANA ROBOTICS** # 502, Rohini Apartments, 8-3-1013/1, Srinagar Colony Main Road, Hyderabad 500073 TS India
1.4. Sponsor's Representative	: YVS Jagannath Technical Head
1.5. Study Facility	: **REVIN LABS PRIVATE LIMITED** Plot No. 84, Road No. 8, 3rd Floor, ALEAP Industrial Area, Gajularamaram, Pragathi Nagar, Hyderabad-500055
1.6. Study Responsibilities	: Mr. Bharath Kumar Head- Microbiology Division

2. STUDY COMPLIANCE

The study was performed:

In accordance with the standard operating procedures at the study facility and as per the mutually agreed with the sponsor.

This study was designed and performed based on below mentioned guideline;

- United States Pharmacopeia (USP)

3. QUALITY ASSURANCE

The quality assurance Head of Revin Labs Pvt. Ltd., has verified the study report and reviewed the raw data and ensure the accurate reflection of the raw data.

4. SAFETY PRECAUTIONS

Chemical resistant gloves, lab coat and lab foot wares will be worn to ensure adequate personnel health and safety.

5. OBJECTIVE

The objective of this study was to evaluate the exposure to Germicidal UV light on different stains.

6. EQUIPMENT INFORMATION

6.1	Model	: UVRova ST
6.2	Reference No.	: UVR-ST01
6.3	Disinfection Type	: Germicidal UV Radiation, 254 nm
6.4	Lamps	: UV High Out
6.5	Safety	: 360°C / temperature sensors
6.6	Foot Print	: 50cm
6.7	Ground Height	: 175cm
6.8	Power	: 220VAC-8A
6.9	UV Dose	: 600-700

7. RESPONSIBILITIES

Name	Designation	Responsibility
Revin Labs Private Limited	**Microbiologist**	The analyst is responsible to Prepare the report of Settle plate method Test activities as per the analysis.
	Head-MB	MB-Head is responsible for the review of the report and ensures that the Settle plate method Test is done as per the stipulated method.
	Head-QA	QA Head is responsible for the review of report and approve.

8. METHODOLOGY

8.1 preparation and standardization of test strains:

8.1.1 Use standardized stable suspensions of test strains or prepared them by seed lot culture maintenance technique so that viable microorganisms used for inoculation are not more than 5 passages master seed lot.

8.1.2 For Inoculum preparation, grow each of the bacterial test strains separately in Soyabean Casein Digest broth or on Soyabean Casein Digest Agar & incubate at 30-35 °C for 18-24 hrs.

8.1.3 Grow the test strain for Candida albicans on Sabouraud Dextrose Agar or Sabouraud Dextrose broth & incubate at 20-25 °C for 2-3 days.

8.1.4 Grow the test strain of *Aspergillus niger* on Sabouraud Dextrose Agar or Sabouraud Dextrose broth & incubate at 20-25 °C for 5-7 days or until good sporulation achieved.

8.1.5 Use buffered sodium chloride – peptone solution pH 7.0 or phosphate buffer solution pH 7.2 to make test suspensions.

8.2 Standardization of culture:

8.2.1 Standardize the culture suspension by serial dilution as follows :

a) 10ml of culture/spore suspension + 90 ml diluents---- A (10^{-1} dilution)

b) 10ml of A + 90 ml diluent----------B (10^{-2}dilution)

c) 10ml of B + 90 ml diluent----------C (10^{-3} dilution)

d) 10ml of C + 90 ml diluent----------D (10^{-4} dilution)

e) 10ml of D + 90 ml diluent----------E (10^{-5} dilution)

f) 10ml of E + 90 ml diluent----------F (10^{-6} dilution)

g) 10ml of F + 90 ml diluent----------G (10^{-7} dilution)

8.2.2 Take 1.0 ml of each dilution from 10^{-5} to 10^{-7} in each sterilized petri plates. Perform the test in duplicate, add 15-20ml of sterilized molten Soyabean Casein Digest agar for bacterial culture and Sabouruad Dextrose agar for yeast and mold cultures in each plate.

Note: If 10 – 100 cfu not obtained from 10^{-5} to 10^{-7}dilution, plating shall be done from lesser or higher dilutions. Incubate the plates at 30-35^0 C for 24 to 48hrs for bacterial culture and at 20-25^0 C for yeast and mold for 72 to 120 hours.

8.2.3 After completion of incubation period, observed and count the number of colonies. Calculate the mean and record the result.

8.2.4 After observation of the plates, rinse the hand with disinfectant.

8.2.5 Preserve the culture dilution containing the count not more than 100 cfu/ml at 2-8°C. Standardized culture suspension can be use within 10 days after completion of standardization.

8.2.6 Perform the above procedure for each culture to be standardized.

8.2.7 Label each standardized cell suspension as per specimen label mentioned.

S.No.	Organism/Strains	Type	Media	Incubation and Temperature
1	*Escherichia Coli*	ATCC 10231	SCDA	30-35°C for 24 to 48 hours
2	*salmonella Abony*	ATCC 16404	SCDA	30-35°C for 24 to 48 hours
3	*Pseudomonas aeruginosa*	ATCC 8739	SCDA	30-35°C for 24 to 48 hours
4	*Staphylococcus aureus*	ATCC 6538	SCDA	30-35°C for 24 to 48 hours
5	*Klebsiella pneumonia*	ATCC 1705	SCDA	30-35°C for 24 to 48 hours
6	*Clostridium species*	ATCC 19404	SCDA	30-35°C for 24 to 48 hours
7	*Staphylococcus epidermidis*	ATCC 12228	SCDA	30-35°C for 24 to 48 hours

Results: From the above Observation for the specification requirement for the cultures qualification are within limit of (NMT 100 cfu/ml).

8.3 Preparation of Media & Pre incubation

8.3.1 Prepare & sterilize the required quantity of Soyabean Casein Digest agar as per respective.

8.3.2 Aseptically pour about 15 to 20 ml of sterilized Soyabean Casein Digest agar in to sterile 90 mm Petri plates under Laminar Air Flow. Allow the medium to solidify.

8.3.3 Check the Growth Promoting properties of Soyabean Casein Digest agar as per respective invert & incubate the plate at 30 to 35°C for 48 hours (Pre incubation)

8.3.4 After incubation check the Petri plates for any contamination. Discard the contaminated Petri plates.

8.3.5 Store the good plates at 20 -25 °C & utilize the plates as per requirement.

8.4 Environmental Monitoring procedure

8.4.1 **Settle Plate Method (Passive Air Sampling)**

8.4.1.1 Mark the location, plate number & date of exposure on the bottom of the Petri plates as per the respective location maps.

8.4.1.2 Take the required number of Petri plates from pre incubator.

8.4.1.3 And expose the plate for 4 hours at specified location.

8.4.1.4 Raise lid to expose the surface of the agar medium, rest lid on the edge of the plate so that the entire surface of agar is exposed.

8.4.1.5 Expose the plate on flat surface of individual SS stand only. (Do not expose the plate on floor) After completion of exposure time, close & collect the plates from respective location.

8.4.1.6 Incubate all Soyabean casein digest agar plates at 20 to 25°C for first 3 days & then at 30 to 35°C for next 2 days. At the end of incubation period (5 days), Count the number of colonies of bacteria and Yeast & molds.

8.4.1.7 The disinfection capability was measured at a distance of 3 meters for 10 minutes.

8.5 Exposure of SCDA Agar Plates Under Germicidal UV Light

S.No.	NAME OF THE ORGANISM/STRAINS	ATCC TYPE	CONTACT PERIOD (MINUTES)	CFU/PLATE
1	*E.coli*	ATCC 8739	1	10
			2	06
			5	05
			7	06
			10	03
2	*Salmonella*	ATCC 14028	1	19
			2	16
			5	14
			7	14
			10	4
3	*P.aeruginosa*	ATCC 9027	1	16
			2	15
			5	15
			7	11
			10	3
4	*S.aureus*	ATCC 6538	1	13
			2	09
			5	10
			7	09
			10	4
5	*Klebsiella*	ATCC 1705	1	11
			2	11
			5	09
			7	08
			10	02
6	*Clostridium*	ATCC 3584	1	10
			2	11
			5	08
			7	07
			10	03
7	*S.epidermidis*	ATCC 12228	1	16
			2	13
			5	13
			7	08
			10	4

8.6 Log Reduction Criteria

S.No.	NAME OF THE ORGANISM/STRAINS	ATCC TYPE	CONTACT PERIOD (MINUTES)	LOG REDUCTION	REDUCTION %
1	*E.coli*	ATCC 8739	1	3.8061	99.98
			2	4.0280	99.99
			5	4.1072	99.99
			7	4.2080	99.99
			10	**4.3290**	**99.99**
2	*Salmonella*	ATCC 14028	1	3.5473	99.97
			2	3.6219	99.97
			5	3.6799	99.97
			7	3.6799	99.97
			10	**4.2240**	**99.99**
3	*P.aeruginosa*	ATCC 9027	1	3.6088	99.97
			2	3.6369	99.97
			5	3.6369	99.97
			7	3.7716	99.98
			10	**4.3358**	**99.99**
4	*S.aureus*	ATCC 6538	1	3.6922	99.97
			2	3.8519	99.98
			5	3.8061	99.98
			7	3.8519	99.98
			10	**4.2041**	**99.99**
5	*Klebsiella*	ATCC 1705	1	3.7912	99.98
			2	3.7912	99.98
			5	3.8783	99.98
			7	3.9295	99.98
			10	**4.5315**	**99.99**
6	*Clostridium*	ATCC 3584	1	3.7993	99.98
			2	3.7580	99.98
			5	3.8963	99.98
			7	3.9543	99.98
			10	**4.3222**	**99.99**
7	*S.epidermidis*	ATCC 12228	1	3.5882	99.97
			2	3.6784	99.97
			5	3.6784	99.97
			7	3.8893	99.98
			10	**4.1903**	**99.99**

9. ACCEPTANCE CRITERIA (LOG REDUCTION)

LOG REDUCTION	REDUCTION FACTOR	PERCENT REDUCED
1	10	90 %
2	100	99 %
3	1000	99.9 %
4	10000	99.99 %
5	100000	99.999 %
6	1000000	99.9999 %

10. RESULTS

The results shown in the section 8.6 are based on colony forming unit (cfu) conducted with and without UV-light treatment for the different strains.

The study showed a significant 4 log reduction (99.99%) on *Escherichia Coli, Salmonella Abony, Pseudomonas aeruginosa, Staphylococcus aureus, Klebsiella pneumonia, Clostridium Species, Staphylococcus* in 10 minutes at 3 meters distance when they are exposed to the UV-light.

1. PICTORIAL REPRESENTATION OF POSITIVE CONTROL PLATES BEFORE EXPOSURE TO UV LIGHT



SET I

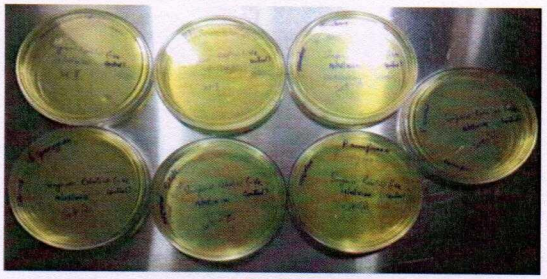


SET II

2. PICTORIAL REPRESENTATION OF TEST (NEGATIVE CONTROL) PLATES BEFORE EXPOSURE TO UV LIGHT



SET I

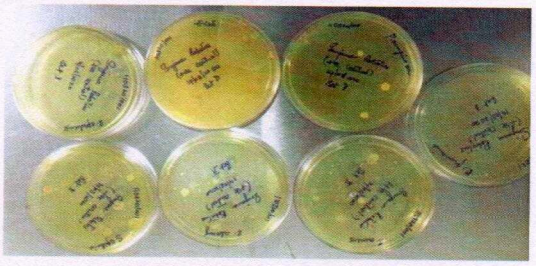


SET II

3. PICTORIAL REPRESENTATION OF POSITIVE CONTROL PLATES AFTER EXPOSURE TO UV LIGHT



SET I



SET II

4. PICTORIAL REPRESENTATION OF TEST (NEGATIVE CONTROL) PLATES AFTER EXPOSURE TO UV LIGHT



SET I



SET II