# QUALIFICATION REPORT
# FOR
# "SATEJ 3Di" VHP GENERATOR USING $H_2O_2$ SILVER SOLUTION

| | | |
|---|---|---|
| **ORGANIZATION NAME** | : | **RADIANT ENTERPRISE** |
| **LOCATION** | : | **C/101, SHIVALIK BUSINESS CENTRE, OFF S.G. HIGHWAY, BODAKDEV. AHMEDABAD -380059, INDIA.** |
| **TESTPARAMETER** | : | **EFFECTIVENESS OF "SATEJ 3Di" VHP GENERATOR FOR MICROBIAL DE CONTAMINATION IN CLEAN ROOMS** |
| **DEPARTMENT PERFORMING QUALIFICATION** | : | **QUALITY CONTROL (MICROBIOLOGY) SHUKRA LABORATORIES** |

**SHUKRA LABORATORIES**
(Unit of Shukra Pharmaceuticals Ltd.)
3rd Floor CAMPS Corner-I
Prahlad Nagar Near AUDA Garden,
AHMEDABAD 380015, Gujarat (INDIA)

| | |
|---|---|
| | **QUALIFICATION REPORT FOR "SATEJ 3Di" VHP GENERATOR USING $H_2O_2$ SILVER SOLUTION** |
| **Department: Quality Control Department** | **Page No.:** 2 of 12 |

## INDEX

## 1.0 Performance Qualification Performed For:

| | | |
|---|---|---|
| ORGANIZATION NAME | : | RADIANT ENTERPRISE |
| LOCATION | : | C/101, SHIVALIK BUSINESS CENTRE, OFF S.G. HIGHWAY, BODAKDEV, AHMEDABAD -380059, INDIA. |

## 2.0 OBJECTIVE

2.1 This report is applicable for Microbial Qualification in Quality Control Department at Shukra Laboratories for "SATEJ 3Di" VHP generator.

## 3.0 SCOPE

3.1 The scope of this document is applicable to verify the Microbial Qualification for effectiveness of "SATEJ 3Di" VHP generator using $H_2O_2$+ silver solution in Quality Control Department at Shukra Laboratories.

## 4.0 DOCUMENTATION PROCEDURE

4.1

- Analytical activities are performed as defined in approved document.
- All documents are completed during the execution of the Qualification.
- Qualification documents created to summaries the execution of test script and in the documents the observation and finding shall be written as per GDP.

## 5.0 DETAILS OF STUDY:

**Equipment Used** : SATEJ 3D i VHP Generator with
Virosil Pharma (H2o2) + silver solution in vapor form
Make: Radiant Enterprise, India.

**Disinfectant Used For Vaporization** : Virosil Pharma (H2O2+ Silver), Product of Sanosil Biotech Ltd, Mumbai. India
Diluted solution of 5% H2O2 and silver.

Total 735ML solution = 367ml VIROSIL PHARMA solution + 367ml of DM water

Solution consumed per 1000cuft:200ml / 1000cuft.

Solution consumed per M3 : 7ml /M3

Location of treatment: Clean room at Shukra laboratories.

**Disinfection Treatment room size in cu.ft.** : 3708 cu.ft. (area size 403.64 sq.ft. x 9.18 ft height)

**Disinfection Treatment room size in M3** : 105 M3 ( Area size 37.5M2 x 2.8 Meter Height)

**Duration of operation for SATEJ 3D i** : 13 minutes

## 6.0 ROLE & RESPONSIBILITY

| | |
|---|---|
| System Owner | - Responsible for all the activities.<br>- Operation of system. |
| Execution Team<br>(Shukra Laboratories ) | - Preparation of documents.<br>- Preparation of media plate and cultures.<br>- Spiking of pathogens.<br>- Monitoring prior to and after treatment.<br>- Incubation and monitoring<br>- Reporting and investigation of deviations if any. |
| QC-Head | - Responsible for review of documents.<br>- Investigation of any deviation and CAPA for the same. |
| QA-Head | - Approval of Qualification Documents. |

## 7.0 EXECUTION

The analysis of Microbial Qualification of Coverall Protective Suit and unstitched Fabricshall be verified by executing the qualification tests as described in this document.

## 7.1 EXECUTION TEAM

| Full Name | Designation | Organization |
|---|---|---|
| Parth Patel | Director | Radiant Enterprise |
| Chirag Shah | Sales Manager | Radiant Enterprise |
| Chitrali Bhatt | Microbiologist | Shukra Laboratories |
| GurpreetKaurSaini | Section Head | Shukra Laboratories |
| Kamlesh Majithiya | Quality Manager | Shukra Laboratories |

## 7.2 ACCEPTANCE CRITERIA

- There shall be significant reduction in load of normal microbial flora.
- There shall be significant reduction in microbial count of forced contaminations of 5 different pathogens applied at multiple locations.

## 8.0 GENERAL DETAILS

## 8.1 MICROBIAL CULTURE DETAILS

| Sr. No. | Name | ATCC No. |
|---|---|---|
| 1.0 | *Escherichia coli* | ATCC8739 |
| 2.0 | *Pseudomonas aeruginosa* | ATCC9027 |
| 3.0 | *Staphylococcus aureus* | ATCC6538 |
| 4.0 | *Bacillus cereus* | ATCC11778 |
| 5.0 | *Candida albicans* | ATCC10231 |

## 8.2 EQUIPMENTS, INSTRUMENTS & ACCESSORIES DETAILS:

| Sr. No. | Name | Make | Model |
|---|---|---|---|
| 1.0 | VHP GENERATOR FOR BIO-DECONTAMINATION | RADIANT ENTERPRISE | SATEJ 3Di |
| 2.0 | BOD INCUBATOR – 1 | THERMOLAB | TB200S/G |
| 3.0 | BOD INCUBATOR –2 | THERMOLAB | TB200S/G |

**9.0 PROCEDURE:**

**9.1 Effectiveness of VHP generator in control of microbial contamination in clean rooms:**

**9.1.1 Culture preparation:**

9.1.1.1 Suspend a loop full of the organisms in 10 ml sterilized saline and dilute serially up to $10^{-8}$.

9.1.1.2 Add 0.1 ml of suspension from dilution $10^{-6}$, $10^{-7}$& $10^{-8}$ for *E. coli, Pseudomonas, Staphylococcus aureus, Bacillus cereus & Candida albicans* on the Soyabean Casein Digest Agar plate in duplicates.

9.1.1.3 Spread the suspension with sterilized spreader on the plate so as evenly distribute the suspension.

9.1.1.4 Incubate the plate at 30- 35°C for 24-48 hours.

9.1.1.5 Select the dilution that gives the count not less than $10^7$ CFU/ml. If required readjust the dilution.

**9.1.2 Plate exposure prior to treatment for normal flora:**

9.1.2.1 Switch off the AHU of respected area that shall be under bio-decontamination process.

9.1.2.2 Close all the vents/openings and doors of the area.

9.1.2.3 Carried out area monitoring by settle plate method to find out initial pre bio-burden of normal micro flora prior to start treatment.

9.1.2.4 Media plates are placed at 4 corners, center and near equipment in the area for 4 hours.

9.1.2.5 After completion of exposure time, placed the lid on plates and send to laboratory for incubation

**9.1.3 Location Identification, spiking and RODAC sampling prior to treatment:**

9.1.3.1 Identified different location in area and spiked known concentration of 5 different pathogens in 10 x 10 cm2 areas in duplicate. (Marked as before and after for RODAC sampling).

9.1.3.2 Contact plate sampling done from all locations by RODAC from block marked as before for pre bio-burden count, placed the lid on plates and send to laboratory for incubation

**9.1.4 Bio decontamination Process using VHP generator SATEJ 3Di & H2O2 based solution(Virosil pharma) :**

9.1.4.1 Prepare the solution for bio-decontamination as directed by the manufacturer and fill the VHP system tank with the prepared solution respectively.

9.1.4.2 Place the VHP system at suitable location in room.

9.1.4.3 Connect the electrical cords of the VHP system to the power supply.

9.1.4.4 Switch on the mains supply and move out of the room, do not enter the room before 60 minutes of completion of bio-decontamination.

**9.1.5 RODAC sampling after to treatment:**

9.1.5.1 Contact plate sampling done from all locations by RODAC from block marked as after for post bio-burden count, placed the lid on plates and send to laboratory for incubation

**9.1.6 Plate exposure after treatment for normal flora:**

9.1.6.1 Carried out area monitoring by settle plate method to find out post bio-burden of normal micro flora after treatment.

9.1.6.2 Media plates are placed at 4 corners, center and near equipment in the area for 4 hours.

9.1.6.3 After completion of exposure time, placed the lid on plates and send to laboratory for incubation

**9.1.7 Area Start Up:**

9.1.7.1 Switch ON the AHU after completion of post bio-decontamination monitoring.

**9.1.8 Incubation, observation and interpretation:**

9.1.8.1 Incubated the Settle plate and RODAC (Contact plates) at respective time and temperatures i.e. 30-35 °C for bacteria and 20-25°C for fungus.

9.1.8.2 Noted down the number of colonies observed after incubation time is over.

9.1.8.3 Results are recorded in defined table and result interpreted based on the observations.

## 9.1.3 OBSERVATION

| Sr. No. | Location | Pathogen | Before count (CFU/Plate) | After count (CFU/Plate) | Effective reduction in % | Reference attachment No. |
|---|---|---|---|---|---|---|
| Surface count by RODAC (Challenged culture) | | | | | | |
| 1 | Ceiling | *Candida albicans* | 25 | 0 | 100.00 | 01 |
| 2 | Floor bottom | | 42 | 2 | 95.24 | 02 |
| 3 | Left wall | | 35 | 0 | 100.00 | 03 |
| 4 | Right wall | | 12 | 0 | 100.00 | 04 |
| 5 | Door | | 38 | 0 | 100.00 | 05 |
| | | | **Overall Effectiveness** | | **99.05** | |
| 6 | Floor bottom | *Escherichia coli* | 56 | 1 | 98.21 | 06 |
| 7 | Ceiling | | 81 | 0 | 100.00 | 07 |
| 8 | Right wall inner | | 46 | 0 | 100.00 | 08 |
| 9 | Front wall | | 72 | 1 | 98.61 | 09 |
| | | | **Overall Effectiveness** | | **99.21** | |
| 10 | Front wall | *Pseudomonas aeruginosa* | 22 | 0 | 100.00 | 10 |
| 11 | Left wall inner | | 30 | 0 | 100.00 | 11 |
| 12 | Floor bottom | | 15 | 0 | 100.00 | 12 |
| 13 | Ceiling | | 21 | 1 | 95.24 | 13 |
| | | | **Overall Effectiveness** | | **98.81** | |
| 14 | Ceiling | *Bacillus cereus* | 91 | 0 | 100.00 | 14 |
| 15 | Floor bottom | | 97 | 2 | 97.94 | 15 |
| 16 | Left wall middle | | 95 | 0 | 100.00 | 16 |
| 17 | Autoclave wall | | 96 | 0 | 100.00 | 17 |
| 18 | Fogger | | 98 | 0 | 100.00 | 18 |
| | | | **Overall Effectiveness** | | **99.59** | |
| 19 | Right wall | *Staphylococcus aureus* | 31 | 0 | 100.00 | 19 |
| 20 | Left wall | | 41 | 0 | 100.00 | 20 |
| 21 | Ceiling | | 80 | 1 | 98.75 | 21 |
| 22 | Floor bottom | | 94 | 2 | 97.87 | 22 |
| 23 | Door | | 92 | 0 | 100.00 | 23 |
| | | | **Overall Effectiveness** | | **99.32** | |
| Air count by settle plate (Normal Flora) | | | | | | |
| 1 | Left Pillar Near Entry | Normal Flora | 65 | 4 | 93.85 | 24 |
| 2 | Left side Front wall | | 31 | 1 | 96.77 | 25 |
| 3 | Right side front wall | | 53 | 4 | 92.45 | 26 |
| 4 | Autoclave corner (Left) | | 44 | 3 | 93.18 | 27 |
| 5 | Centre | | 71 | 6 | 91.55 | 28 |
| 6 | Autoclave corner (Right) | | 42 | 3 | 92.86 | 29 |
| | | | **Overall Effectiveness** | | **93.36** | |

## 10.0 CONCLUSION:

The study shows following outcomes:

1. SATEJ 3D i , vaporised $H_2O_2$ generator kept in one fixed location ensured uniform spread of dry vapor of virosil pharma across the space of 3708cu.ft./105$m^3$.
2. At the end of procedure, ensured that no wetness of on floor, walls, equipments, lights, electronic equipment was observed.
3. The pre and post microbial count results show that there was significant reduction in load of normal microbial flora.
4. Process also shows significant reduction in microbial count of forced contaminations of 5 different pathogens applied at multiple locations.
5. The combination of VHP generator SATEJ 3Di and VIROSIL PHARMA were useful in eliminating microbial load on surfaces and air very effectively.
6. Such method offers many additional benefits and safety which cannot be achieved alone by manual mopping and wiping.

## 11.0 FINAL APPROVAL

| Prepared By | | | | |
|---|---|---|---|---|
| **Department** | **Name** | **Designation** | **Signature** | **Date** |
| **Analyst Shukra Laboratories** | Bhatt Chitrali | Microbiologist | J. Bhatt | 04/08/2021 |
| **Review By** | | | | |
| **Section Head Shukra Laboratories** | Gurpreet Kaur Saini | QC Executive Microbiologist | Gurpreet | 25/08/2021 |
| **QA Shukra Laboratories** | Kinnarei Bakoraniya | Sr. officer QA | [illegible] | 25/08/21 |
| **Executive Radiant Enterprise** | CHIRAG | MANAGER | [illegible] | 21/09/21 |
| **Approved By** | | | | |
| **Quality Manager Shukra Laboratories** | Ramlesh Majithiya | Quality Manager | [illegible] | 26/08/2021 |
| **Head Radiant Enterprise** | PARTH PATEL. | DIRECTOR | [illegible] | 21/9/21 |

## 12.0 ABBREVIATION

| | |
|---|---|
| **GMP** | Good Manufacturing practices |
| **QA** | Quality Assurance |
| **QC** | Quality Control |
| **CFU** | Colony Forming Unit |
| **°C** | Degree Centigrade |
| **SL** | Shukra Laboratories |
| **Pvt.** | Private |
| **Ltd.** | Limited |
| **ml** | Milliliter |

# CERTIFICATE OF ANALYSIS


**SHUKRA LABORATORIES**
TRUSTED FOR LIFE
FDCA LICENCE NO. GTL/37/46
**Form 39 (Rule 150E (f) The Drugs & Cosmetic Act, 1940 and rules there under)**

3rd FLOOR CAMPS CORNER – I, PRAHLADNAGAR, NEAR AUDA GARDEN, AHMEDABAD; GUJARAT; INDIA - 380015
**PhoneNo.:** +079-48931389/2389 **Mobile No.:** 9979868199
**Email:**qc@shukralaboratories.com
**Website:**www.shukralaboratories.com


**CERTIFICATE NO.: SL/CST/OT/210818/039**

| | | | | | |
|---|---|---|---|---|---|
| **NAME OF MANUFACTURER /PARTY/SUBMITTED BY WITH ADDRESS** | : | **RADIANT ENTERPRISE C/101, SHIVALIK BUISNESS CENTRE, OFF S.G. HIGHWAY, BODAKDEV.AHMEDABAD -380059, INDIA.** | | | |
| **NAME OF SAMPLE /EQUIPMENT** | : | **"SATEJ 3Di" VHP GENERATOR** | **INWARD NO./A.R. NO.** | : | **SL/CST/OT/210818/039** |
| **NAME OF SAMPLE/ DISINFECTANT SOLN** | | **VIROSIL PHARMA** | | | |
| **GENERIC NAME** | : | **NA** | **SUPPLIED BY** | : | **RADIANT ENTERPRISE** |
| **BATCH NO./LOT NO.** | : | **NA** | **RECEIVED BY** | : | **SHUKRA LABORATORIES** |
| **REFERENCE NO.** | : | **NM** | **MFG. DATE/EXP.DATE** | : | **NA** |
| **MFG.LIC NO.** | : | **NM** | **BATCH SIZE** | : | **NA** |
| **SAMPLE QTY.** | : | **1NO EQUIPMENT 735ML SOLUTION (367 ML VIROSIL PHARMA + 368ML OF DM WATER)** | **SAMPLE CONDITION** | : | **NA** |
| **SAMPLE ID NO.** | : | **NA** | **SAMPLE TYPE** | : | **VHPGENERATOR SATEJ 3Di WITH DILUTED H2O2 SOLUTION (VIROSILPHARMA )** |
| **ANALYSIS START DATE** | : | **18/08/2021** | **ANALYSIS END DATE** | : | **24/08/2021** |

## RESULT OF TEST

| SR. NO. | PATHOGEN | UNIT | RESULT | | | | | | METHOD OF TEST |
|---|---|---|---|---|---|---|---|---|---|
| | | | Location | I | II | III | IV | V | |
| **Surface count by RODAC (Challengeculture)** | | | | | | | | | |
| 1.1 | *Candida albicans* | CFU | Before | 25 | 42 | 35 | 12 | 38 | As per In-House |
| | | | After | 0 | 2 | 0 | 0 | 0 | |
| | | | Effectiveness | 99.05 % | | | | | |
| 1.2 | *Escherichia coli* | CFU | Before | 56 | 81 | 46 | 72 | NA | As per In-House |
| | | | After | 1 | 0 | 0 | 1 | NA | |
| | | | Effectiveness | 99.21 % | | | | | |
| 1.3 | *Pseudomonas aeruginosa* | CFU | Before | 22 | 30 | 15 | 21 | NA | As per In-House |
| | | | After | 0 | 0 | 0 | 1 | NA | |
| | | | Effectiveness | 98.81 % | | | | | |
| 1.4 | *Bacillus cereus* | CFU | Before | 91 | 97 | 95 | 96 | 98 | As per In-House |
| | | | After | 0 | 2 | 0 | 0 | 0 | |
| | | | Effectiveness | 99.59 % | | | | | |
| 1.5 | *Staphylococcus aureus* | CFU | Before | 31 | 41 | 80 | 94 | 92 | As per In-House |
| | | | After | 0 | 0 | 1 | 2 | 0 | |
| | | | Effectiveness | 99.32 % | | | | | |

| SR. NO. | PATHOGEN | UNIT | RESULT | | | | | | | METHOD OF TEST |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Location | I | II | III | IV | V | VI | |
| **Air count by Settle Plate (Normal Flora)** | | | | | | | | | | |
| 2.1 | *Normal Flora* | CFU | Before | 65 | 31 | 53 | 44 | 71 | 42 | As per In-House |
| | | | After | 4 | 1 | 4 | 3 | 6 | 5 | |
| | | | Effectiveness | 93.36 % | | | | | | |

SHUKRA

**Certificate:** In the opinion of undersigned the sample reffered to above is of standard quality with respect to defined in the act and the rules made there under.

**Note (1):Equipment VHPgenerarator SATEJ 3Di used with H2O2 based disinfectant (Virosil Pharma ) found very effective against different microbial organisams.**

**Note (2):Test is carried out as per In-House Method using various Microbes as challenge organism for 60 Minutes bio-decontamination Time.(Room Size 3708 cubic ft = 105 Cubic Meters)**

**Release Date: 24/08/2021**

| CHECKED BY | | APPROVED BY/AUTHORIZED BY |
|---|---|---|
| 24/08/2021 | SHUKRA LABORATORIES AHMEDABAD | 24/08/2021 |
| AJAZ MEMON | | DIVYESH MODI |
| ASST. MANAGER | | MANAGER |

Note:

1. The test result refer only to the tested sample and application parameters, Endorsement of the product is neither referred nor impied.
2. Total liability of our institution is limited to the invoice amount/testing charges.
3. This report is not to be reproduced wholly or in part and cannot be used as an evidence in the court of law and should not be used in any adverting media without our special permission in writing.
4. Sample analysis/testingare performed on request of customers and on the sample drawn & submitted be the party for analysis unless otherwise stated.
5. Shukra laboratories maintains strict confidentiality of all the analysis and test results of sample received and will not reveal this information to third party unless required by the staturory or legal requirement.
6. All sample swould be destroyed after one month from the date of report/unless otherwise agreed with the customer. Also retain sample will not be returned unless otherwise agreed in writing.
7. The sample is acceptable by us subject to our general conditionsof services which is available on request. Attention is drawn to the limitation of liabilities.