

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

| STANDARD OPERATING PROCEDURE | | | | |
|---|-----|------------------------|--------------|--|
| Title: Evaluation of efficiency of UV light on microbial cultures | | | | |
| SOP No.: | | Department: | Microbiology | |
| | | Effective Date: | | |
| Revision No.: | 00 | Revision Date: | | |
| Supersede Revision No.: | Nil | Page No.: | 1 of 3 | |

- 1. **Purpose:** The purpose of this SOP is to provide the procedure for evaluation of efficiency of UV light on microbial cultures.
- 2. **Scope:** This SOP is applicable for evaluation of efficiency of UV light on microbial cultures in the Microbiology Section.

3. References, Attachments & Annexures:

3.1. **References:**

- 3.1.1. In-house
- 3.1.2. SOP Operation, Performance check, Sanitization and Qualification of Laminar Air Flow Unit

3.2. Attachments:

3.2.1. Attachment-1: Evaluation of efficiency of UV light on microbial cultures

3.3. Annexures: None

4. **Responsibilities:**

4.1. Microbiologist:

- 4.1.1. To perform the activity as per SOP.
- 4.1.2. To maintain all the records as per SOP.

4.2. QC Head or designee:

- 4.2.1. To check the SOP.
- 4.2.2. To give training to all concerned persons before implementation of SOP.

4.3. Quality Assurance:

- 4.3.1. To check the SOP.
- 4.3.2. To ensure the implementation of system as per SOP.

4.4. Regulatory Affairs, Quality Head , Plant Head:

4.4.1. To review and approve the SOP.

5. Distributions:

- 5.1. Quality Control (Microbiology)
- 5.2. Quality Assurance

6. **Definitions of terms & Abbreviations:**

6.1. **Definitions of terms:**None



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6.2. Abbreviations:

- 6.2.1. **SOP** : Standard Operating Procedure
- 6.2.2. No. : Number
- 6.2.3. **QA** :Quality Assurance
- 6.2.4. **QC** :Quality Control
- 6.2.5. NA : Not Applicable
- 6.2.6. UV : Ultra violet
- 6.2.7. °C : Degree Celsius
- 6.2.8. % : Percent

7. **Procedure:**

7.1. General:

7.1.1. Streak standard cultures of *Bacillus subtilis* (spore formers), *Pseudomonas* aeruginosa (non-spore former) and *Aspergillus niger* (Fungi) on agar media (Soyabean Casein Digest Agar for bacteria and Sabouraud Dextrose agar for fungi).

- 7.1.2. Switch on the LAF as per SOP and expose the plates having inoculums under UV light to glow.
- 7.1.3. Let the plates to be exposed at 5,10,15 and 20 minutes.
- 7.1.4. After exposure incubate the plates for bacteria at 30-35°C (for 120 hours) and 20-25°C (for120 hours) for fungi.
- 7.1.5. Keep one each streaked plate unexposed as positive control & one each unstreaked plate unexposed as negative control.
- 7.1.6. Note down the results of growth after incubation in attachment-1
- 7.1.7. The above study shall be carried out for 3 successive readings.

7.2. Acceptance criteria:

After incubation no growth should be observed on inoculated plates after 15 minutes .

7.3. Frequency:

7.3.1. When new installation of UV light takes place.



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Attachment-1 Evaluation of efficiency of UV light on microbial cultures

| Name of instru | ment: | | Date of analysis: | | | |
|-------------------------------------|----------------------------------|-------------|-------------------|----------|--|--|
| Instrument ID No.: | | | Date of result: | | | |
| Soyabean Case | in Digest Agar lot N | No.: | | | | |
| Sabouraud Des | Sabouraud Dextrose Agar lot No.: | | | | | |
| | Observation | | | | | |
| | Exposure time | B. subtilis | P. aeruginosa | A. niger | | |
| | 5 minutes | | | | | |
| Reading I | 10 minutes | | | | | |
| | 15 minutes | | | | | |
| | 20 minutes | | | | | |
| | 5 minutes | | | | | |
| | 10 minutes | | | | | |
| Reading II | 15 minutes | | | | | |
| | 20 minutes | | | | | |
| | 5 minutes | | | | | |
| | 10 minutes | | | | | |
| Reading III | 15 minutes | | | | | |
| | 20 minutes | | | | | |
| Positive Control: Negative Control: | | | | | | |
| Conclusion: | | | | | | |
| Done by: | | Che | ecked by: | | | |
| Date: | | Dat | æ: | | | |

8. History:

| Version No. | Effective Date | |
|-------------|----------------|--|
| | | |