PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Evaluation of Efficiency of UV light on microbial cultures	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 PURPOSE:

To lay down the procedure for evaluation of UV Light efficacy, so as to demonstrate the effective germicidal action of the UV light.

2.0 SCOPE:

This Standard Operating Procedure is applicable at Microbiology Department of .....

3.0 REFERENCES:

3.1 In – house

3.2 SOP “Preparation of Microbial Culture Suspension”

3.3 SOP “Preparation, Sterilization and Qualification of the Media.”

4.0 RESPONSIBILITY:

4.1 Officer or Executive of Microbiology department shall be responsible for preparation of new or revision of existing SOP’s.

4.2 Head of the department/designee of respective areas & QA shall be responsible for reviewing the SOP’s.

4.3 Plant Head and Head-Quality shall be responsible for approval of SOP.

4.4 QA shall be responsible for distribution and control of SOP’s to various departments.

5.0 ABBREVIATIONS:

5.1 CC : Change Control

5.2 CFU : Colony Forming Unit

5.3 °C : Degree Celsius

5.4 COA : Certificate of analysis

5.5 LAF : Laminar Air Flow

5.6 ml : Millilitre

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Evaluation of Efficiency of UV light on microbial cultures	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.7 NA : Not Applicable

5.8 No. : Number

5.9 QA : Quality Assurance

5.10 QC : Quality Control

5.11 SOP : Standard Operating Procedure

5.12 SCDA : Soyabean Casein Digest Agar

5.13 UV : Ultra Violet

5.14 µm : Micrometer

6.0 DEFINITION:

6.1 **Standard Operating Procedure (SOP):** A written authorized procedure, which gives instructions for performing operations.

7.0 PROCEDURE:

7.1 Precaution:

7.1.1 Do not look into the UV light when it is switched ON.

7.1.2 Supplier COA of each UV light tube should be checked (if available).

7.2 Validation/Qualification:

7.2.1 Prepare SCDA media as per the Current version of "Preparation, Sterilization and Qualification of the Media."

7.2.2 Sterilize the media as per the validated cycle and transfer it to LAF. Allow the media to cool up to 45°C.

7.2.3 Pour approximately 15 - 20 ml of media aseptically in sterilized Petri plate and allow them to solidify.

7.2.4 Mark 22 plates with name of one culture & date. Make set of 5 marked plates & mark them 5 min, 15 min, 30 min and 45 min per set. Mark 2 of the plates as positive control plates.

7.2.5 Prepare & Keep two SCDA plate without inoculation as Negative control.

7.2.6 Prepare culture suspensions containing 10-100 cfu's as per current version of SOP "Preparation of Microbial Culture Suspension".

7.2.7 Inoculate 22 SCDA plates each with 1ml volume of suspension containing 10-100 cfu's of *Bacillus subtilis* under Biosafety cabinet.

7.2.8 Do not expose positive control plates to UV light, these plates shall serve as the initial count.

7.2.9 Expose the plates as per the time mentioned in Annexure-1 (i.e. 5 min., 15 min., 30 min. and 45 min). Use a calibrated stopwatch to check the exposure time.

7.2.10 Expose the first set of 5 plates as per locations mentioned in Annexure-2 & switch on the UV light for 5 minutes.

7.2.11 After 5 minutes collect the plates.

7.2.12 Expose the second set of plate on the same locations & switch on the UV light for 15 minutes.

7.2.13 Switch "OFF" the UV Light while replacing the plates in between.

7.2.14 Repeat the procedure for rest of the time periods for *Bacillus subtilis*.

7.2.15 Repeat the whole exercise for *S. aureus, Candida albicans, A. niger* & EM Isolate.

7.2.16 Incubate all the Exposed, Negative & positive control plates at 30-35°C for 72 hrs.

7.2.17 After completion of incubation period, note down the results as per the Annexure-3.

7.2.18 UV Light shall be replaced positively after 1000 hrs.

7.3 Acceptance Criteria for UV light Efficacy: ≥1 log reduction in 30 Minutes.

7.4 The minimum exposure time required under UV Light shall be decided on the basis of the observation of the test conducted.

8.0 DISTRIBUTION:

8.0 Quality Assurance

8.1 Quality Control

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Evaluation of Efficiency of UV light on microbial cultures	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

9.0 ANNEXURES:

9.1 Annexure-1: UV Light Validation Plan.

9.2 Annexure-2: Plate exposure Location for UV Light Validation.

9.3 Annexure-3: UV Light Efficacy Validation report.

10.0 REVISION HISTORY:

Version Number	Revision Details	Effective Date	Ref. Change Control Number
			-