RISK ASSESSMENT

ANNEXURE-2 (AFTER QUALIFICATION)

System Name: UV   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Mitigation Action Performed
A. Unauthorized System Access								
1.	Unauthorized person tries to log into system	Unauthorized persons may damage the system	High	Low	2	High	Low	System is password Protected. Unathorized Person log in test Verified in Operational Qualification Point No.12.4 & Point No 12.5.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT
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System Name: UV   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Mitigation Action Performed
B. PC Power Failure								
1.	Power failure during operation	Data may be lost and system may get damaged which may lead to affect Product quality	High	Low	2	High	Low	After power resumption, system was started and authorized person can access the system. Data remained same after power failure. No damage found in system after power loss. Verified in Operational Qualification Point No.12.7

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

RISK ASSESSMENT
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Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Mitigation Action Performed
C. Window Security								
1.	Unauthorized person tries to log into Window	Unauthorized persons may damage the window	High	Medium	1	Medium	High	Window shall be password Protected. Unathorized Person log in shuould not be granted. Verified in Operational Qualification Point No.12.2.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

Document No.:

RISK ASSESSMENT
ANNEXURE-2 (AFTER QUALIFICATION)

System Name: UV   **System ID:**

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D. Communication Failure								
1.	Communication fail between CPU and Monitor	1. Data may be losses and system operation control is lost. 2. User cannot operate the operation.	High	Low	2	High	Low	Monitor should display error message or monitor should not response. Printing command should not reached to printer. Verified in Operational Qualification Point No.12.7.

Verified by: _____   Date: _____

Reviewed by: _____   Date: _____

RISK ASSESSMENT
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E. Hardware Failure								
1.	Failure of hardware (PC)	In case of hardware (PC) failure, all process shall be stopped.	High	Low	2	High	Low	Hardware accessories make were standard and designed as per system specifications. Spare parts of hardware and accessories were available and it is one to one replaceable. Verified in Operational Qualification Point No.12.7.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

Document No.:

RISK ASSESSMENT
ANNEXURE-2 (AFTER QUALIFICATION)

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F. Physical security of system								
1.	Unauthorized person tries to operate the system.	In case system not physical secure the electronic componets damage or loss	High	Medium	1	Medium	High	System shall be physically secure. Verified in Installation Qualification Point No.12.6 & 12.11.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

RISK ASSESSMENT

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G. Improper Training and Procedure								
1.	Untrained operator tries to operate the system	System may get damage or lose	High	Low	2	High	Low	System is password Protected. Only authorized persons access the system. Operator are trained for operation of system. Verified in Operational Qualification Point No.12.2 & 12.5.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT
ANNEXURE-2 (AFTER QUALIFICATION)

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Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Mitigation Action Performed
2.	Operation SOP or master documents does contain proper information	System may get damage or lose	High	Low	2	High	Low	Standard Operating Procedure for UV. Contain proper information available in SOP. Verified in Installation Qualification Point No. 12.2 & Point No. 12.12.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____

RISK ASSESSMENT
ANNEXURE-2 (AFTER QUALIFICATION)

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Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Mitigation Action Performed
H. Audit Trial Failure								
1	Failure of Login, Logout and Login Fail entry into the report	May lead to Data integrity	High	Low	2	High	Low	Failure of Login, Logout and Login Fail is update in the report Verified in Operational Qualification Point No. 12.9.
2.	Report Edition	May lead to Data integrity	High	Low	2	High	Low	Users are not able to Edition in report Verified in Operational Qualification Point No.12.10.

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Reviewed by: _____   Date : _____

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I. Authorized System Access								
1	Authorized person (Operator/Supervisor/QA/Manager /Manufacturer Admin) tries to change the date and time	Ambiguity of data may arise	High	Low	2	High	Low	Date and time are password protected. Verified in Operational Qualification Point No.12.11.
2.	Authorized person (Operator/Supervisor/QA/Manager / Manufacturer Admin) tries to access to data storage folder	Ambiguity of data may arise	High	Low	2	High	Low	System have specific Path and limited access for Data Storage. Verified in Operational Qualification Point No.12.12.

Verified by: _____   Date : _____

Reviewed by: _____   Date : _____