

PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

System Name: UV

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:										
Review	ved by:							Date:		
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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 Operationa Qualification Point No.12.7
Verifie	d by:	·						Date:
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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 Operationa Qualification Point No.12.2.		
Verifie	d by:							Date:		
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System Name: UV System ID: Risk Risk **Probability** Risk **Identified Risk** ID Impact Severity **Probability Mitigation Action Performed** Class of Detection Priority No. **D.** Communication Failure Monitor should display error 1. Data may be losses and system message or monitor should not Communication operation control response. fail between is lost. Printing command should not CPU and 2 1. High Low High Low 2. User cannot Monitor reached to printer. operate the Verified in Operational operation. Qualification Point No.12.7. Date:_____ Verified by: _____ Reviewed by: _____ Date: Page 4 of 10 **Document No.:**



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F. Phys	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:												
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RISK ASSESSMENT

PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

ANNEXURE-2 (AFTER QUALIFICATION)

System Name: UV System ID: Risk Risk **Probability** Risk **Identified Risk** ID Impact Severity **Probability Mitigation Action Performed** Class of Detection Priority No. **G. Improper Training and Procedure** System is password Protected. Only authorized persons access Untrained the system. operator tries to Operator are trained for System may get High 2 1. operate the Low High Low operation of system. damage or lose system Operational Verified in Qualification Point No.12.2 & 12.5. Date:_____ Verified by: _____ Reviewed by: _____ Date: Page 7 of 10 **Document No.:**



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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.			
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System Name: UV System ID: Risk Risk **Probability** Risk **Identified Risk** ID Impact Severity **Probability Mitigation Action Performed** Class of Detection **Priority** No. H. Audit Trial Failure Failure of Login, Logout and Failure of Login, Login Fail is update in the report Logout and May lead to Data High 2 High 1 Low Low Verified in Operational Login Fail entry integrity into the report Qualification Point No. 12.9. Users are not able to Edition in May lead to Data report 2. **Report Edition** High 2 High Low Low Verified in integrity Operational Qualification Point No.12.10. Date: Verified by: _____ Reviewed by: _____ Date: Page 9 of 10 **Document No.:**



System Name: UV

RISK ASSESSMENT ANNEXURE-2 (AFTER QUALIFICATION)

PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

Risk Risk **Probability** Risk ID **Identified Risk Probability Mitigation Action Performed** Impact Severity Class of Detection Priority No. I. Authorized System Access Authorized person (Operator/Supervis Date and time are password or/QA/Manager protected. Ambiguity of /Manufacturer High 2 High 1 Low Low Verified data may arise in Operational Admin) tries to Qualification Point No.12.11. change the date and time Authorized person (Operator/Supervis System have specific Path and or/QA/Manager / limited access for Data Storage. Ambiguity of 2. Manufacturer High Low 2 High Low data may arise Verified in Operational Admin) tries to Qualification Point No.12.12. access to data storage folder Verified by: _____ Date:_____ Reviewed by: _____ Date: Page 10 of 10 **Document No.:**