



PHARMADEVILS

IT DEPARTMENT

[Appendix 2a-Template of URS/ SRS]

**Title: System Requirement Specification/User Requirement Specification for
< Equipment/ System >**

Document No.:

<Document No.>

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**System Requirement Specification
for
<System Name>**



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APPROVAL PAGE

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REVISION HISTORY

Revision No.	Effective Date	Reason for Revision
		Initial Document



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1.0 INTRODUCTION:

2.0 OBJECTIVE:

3.0 SCOPE:

4.0 REFERENCES:

Document Number/ Name	Description

5.0 RESPONSIBILITY:

Role	Responsibility

6.0 SYSTEM OVERVIEW:

7.0 CONFIGURATION REQUIREMENT:

Req. No.	Requirement Description

8.0 TECHNICAL REQUIREMENTS:

Req. No.	Requirement Description

9.0 OPERATIONAL/ FUNCTIONAL REQUIREMENTS:

Req. No.	Requirement Description

10.0 DATA REQUIREMENTS:

The data on which the system is to work and all regulatory requirements should be described. The following aspects should be addressed as appropriate:

10.1 AUDIT TRIAL REQUIREMENTS

Req. No.	Requirement Description



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10.2 DATA BACKUP, RESTORATION AND ARCHIVAL REQUIREMENT

Req. No.	Requirement Description

10.3 DATA MIGRATION REQUIREMENTS

Req. No.	Requirement Description

11.0 LIFE CYCLE REQUIREMENTS

11.1 DOCUMENTATION REQUIREMENTS

Req. No.	Requirement Description

11.2 STANDARD OPERATING PROCEDURES

Req. No.	Requirement Description

12.0 REGULATORY REQUIREMENTS

Req. No.	Requirement Description

13.0 ABBREVIATIONS: