

Standard Operating Procedure VAL 075

Title: Validation Deviation Management

Appendix 1

Appendix [Insert Appendix No] DEVIATION LOG AND REPORT

The following log sheet is to be filled out in the event that any deviations occurred in this protocol. For each deviation enter the Test Number where the deviation was found, a description of that deviation and whether it was critical or non-critical (C or N respectively).

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| Dev. # | Test Number | Deviation | C or N | Initials/Date |
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APPENDIX [Insert Appendix No] – DEVIATION LOG AND REPORT

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|---|---------------------------|-------------------------------|-------------------------------|-----------------------|-----------|-----------------------|-----------------------|
| DEVIATION REPORT NO.: | | | | | | | |
| TEST SCRIPT / TEST PROCEDURE #: | | | | | | | |
| <p>1. DEVIATION DESCRIPTION:</p> | | | | | | | |
| | | | | | | | Initial / Date |
| <i>Circle Classification</i> | Critical Deviation | Non-Critical Deviation | <i>Circle Change Required</i> | Yes Change # | No | QAR # ----- | COMMITMENT # |
| <p>2. RESOLUTION (attach any re-test results to this sheet):</p> | | | | | | | |
| Resolution Completed & Deviation Resolved: (yes/no) | | | | Initial / Date | | | |
| <p>3. JUSTIFICATION FOR ACCEPTANCE OF DEVIATION:</p> | | | | | | | |
| Justification Completed & Deviation Accepted: (yes/no) | | | | Initial / Date | | | |
| | Print/Type Name | Signature | Date | | | | |
| Approved By: (System Owner) | | | | | | | |
| Approved By: (Validation) | | | | | | | |
| Approved By: (Quality Assurance) | | | | | | | |

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