**Traceability Matrix**

(Reference SOP: _____)

1. **Purpose**
   The Traceability Matrix
   - Records the relationship between two or more products of the design and development process.
   - Ensures that all requirements are met and can be traced to the appropriate design elements.
   - Ensures all requirements are verified and can be traced to a test or verification activity that shows that requirements have been met.

2. **Traceability Matrix**

<table>
<thead>
<tr>
<th>URS (User Requirement Specification Reference Number)</th>
<th>Description</th>
<th>Scope</th>
<th>GxP or regulatory Impact</th>
<th>Other Impact (Business or Safety)</th>
<th>Functional Specification Reference</th>
<th>Design Specification Reference</th>
<th>Testing Required</th>
<th>Test or Verification Reference</th>
<th>How requirement met</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>All User Requirements need to be listed</td>
<td>Include the Full URS section or brief reference and keywords, i.e Audit Trail, security</td>
<td>The scope that this URS section effects. This will also identify who has responsibility for maintaining</td>
<td>If there is a GxP or ER/ES, or other Regulatory impact, then there should be a test reference number in</td>
<td>The system may require formal verification or testing for other reasons other than GxP, e.g financial, Safety for</td>
<td>Enter the FS that defines the URS section. If the URS will not be satisfied by the system this should be made clear by an appropriate notation, such as 'Not Met' or an SOP reference</td>
<td>Enter the Design Spec or Configuration that satisfies the FS</td>
<td>(Y or N)</td>
<td>If Y then a test reference should be made in the test reference column. If No then</td>
<td>A reference to a specific test should be included where there is a GxP impact or any other impact. Completion of the column is required in order to trace all Requirements to</td>
<td>Some requirements may be met by means other than verification, software and additional testing or Were the requirements</td>
</tr>
</tbody>
</table>