# LIST OF TABLES

## CHAPTER-1

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Impurity classification based on ICH guidelines - Q3A(R), [1] Q3B (R), [2] and Q3C [3].</td>
<td>6</td>
</tr>
<tr>
<td>1.2</td>
<td>ICH reporting, identification and qualification threshold for organic impurities in drug substance.</td>
<td>7</td>
</tr>
<tr>
<td>1.3</td>
<td>Thresholds for Degradation Products in Drug Products</td>
<td>7</td>
</tr>
<tr>
<td>1.4</td>
<td>Functional groups susceptible to hydrolysis in drugs</td>
<td>11</td>
</tr>
<tr>
<td>1.5</td>
<td>Functional groups susceptible to oxidative degradation in drugs</td>
<td>13</td>
</tr>
<tr>
<td>1.6</td>
<td>Flow-chart for identification of unknown impurities in drugs.</td>
<td>27</td>
</tr>
<tr>
<td>1.7</td>
<td>Tolerance criteria for method validation parameters.</td>
<td>45</td>
</tr>
</tbody>
</table>

## CHAPTER-2

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>% Degradation products of Lenalidomide against their corresponding HPLC RRT's and conditions, observed under forced degradation studies.</td>
<td>56</td>
</tr>
<tr>
<td>2.2</td>
<td>Results of Precision and Accuracy at LOQ level</td>
<td>69</td>
</tr>
<tr>
<td>2.3</td>
<td>Results of Detector Response linearity</td>
<td>70</td>
</tr>
<tr>
<td>2.4</td>
<td>System suitability parameters for Lenalidomide.</td>
<td>71</td>
</tr>
<tr>
<td>2.5</td>
<td>Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies for Imp-C.</td>
<td>72</td>
</tr>
<tr>
<td>2.6</td>
<td>Accuracy (Recovery test)</td>
<td>73</td>
</tr>
<tr>
<td>2.7</td>
<td>Robustness results</td>
<td>78</td>
</tr>
</tbody>
</table>

## CHAPTER-3

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>RRT; RRF values and LOD-LOQ</td>
<td>85</td>
</tr>
<tr>
<td>3.2</td>
<td>% Degradation products against their corresponding HPLC RRT's and conditions, observed under forced degradation studies</td>
<td>88</td>
</tr>
<tr>
<td>3.3A</td>
<td>Results of Topotecan RF</td>
<td>107</td>
</tr>
<tr>
<td>3.3B</td>
<td>Results of Imp-A RRF</td>
<td>107</td>
</tr>
<tr>
<td>3.3C</td>
<td>Results of Imp-B RRF</td>
<td>107</td>
</tr>
<tr>
<td>3.3D</td>
<td>Results of Imp-C RRF</td>
<td>108</td>
</tr>
<tr>
<td>3.4A</td>
<td>Results of Precision and Accuracy at LOQ level for Topotecan.</td>
<td>109</td>
</tr>
<tr>
<td>3.4B</td>
<td>Results of Precision and Accuracy at LOQ level for Imp-A.</td>
<td>109</td>
</tr>
<tr>
<td>3.4C</td>
<td>Results of Precision and Accuracy at LOQ level for Imp-B.</td>
<td>109</td>
</tr>
<tr>
<td>Table</td>
<td>Description</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Table 3.4D</td>
<td>Results of Precision and Accuracy at LOQ level for Imp-C.</td>
<td>109</td>
</tr>
<tr>
<td>Table 3.5A</td>
<td>Results of Linearity for Imp-A.</td>
<td>111</td>
</tr>
<tr>
<td>Table 3.5B</td>
<td>Results of Linearity for Imp-B.</td>
<td>111</td>
</tr>
<tr>
<td>Table 3.5C</td>
<td>Results of Linearity for Imp-C.</td>
<td>112</td>
</tr>
<tr>
<td>Table 3.5D</td>
<td>Results of Linearity for Topotecan.</td>
<td>112</td>
</tr>
<tr>
<td>Table 3.6</td>
<td>Results of system suitability parameters for Topotecan</td>
<td>113</td>
</tr>
<tr>
<td>Table 3.7A</td>
<td>Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies for Imp-A.</td>
<td>114</td>
</tr>
<tr>
<td>Table 3.7B</td>
<td>Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies for Imp-B.</td>
<td>114</td>
</tr>
<tr>
<td>Table 3.7C</td>
<td>Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies for Imp-C.</td>
<td>114</td>
</tr>
<tr>
<td>Table 3.8A</td>
<td>Accuracy results for Imp-A</td>
<td>116</td>
</tr>
<tr>
<td>Table 3.8B</td>
<td>Accuracy results for Imp-B</td>
<td>117</td>
</tr>
<tr>
<td>Table 3.8C</td>
<td>Accuracy results for Imp-C</td>
<td>118</td>
</tr>
<tr>
<td>Table 3.8D</td>
<td>Accuracy results for Imp-A [Calculated by using slope/intercept values]</td>
<td>119</td>
</tr>
<tr>
<td>Table 3.8E</td>
<td>Accuracy results for Imp-B [Calculated by using slope/intercept values]</td>
<td>120</td>
</tr>
<tr>
<td>Table 3.8F</td>
<td>Accuracy results for Imp-C [Calculated by using slope/intercept values]</td>
<td>121</td>
</tr>
<tr>
<td>Table 3.8G</td>
<td>Regression plot for Impurity-A</td>
<td>122</td>
</tr>
<tr>
<td>Table 3.8H</td>
<td>Regression plot for Impurity-B</td>
<td>123</td>
</tr>
<tr>
<td>Table 3.8I</td>
<td>Regression plot for Impurity-C</td>
<td>124</td>
</tr>
<tr>
<td>Table 3.8J</td>
<td>Range for the Slope &amp; Y- Intercept values for Imp-A, Imp-B &amp; Imp-C.</td>
<td>125</td>
</tr>
<tr>
<td>Table 3.9A</td>
<td>Results of solution stability of Topotecan</td>
<td>127</td>
</tr>
<tr>
<td>Table 3.9B</td>
<td>Results of solution stability of Imp-A</td>
<td>128</td>
</tr>
<tr>
<td>Table 3.9C</td>
<td>Results of solution stability of Imp-B</td>
<td>128</td>
</tr>
<tr>
<td>Table 3.9D</td>
<td>Results of solution stability of Imp-C</td>
<td>129</td>
</tr>
<tr>
<td>Table 3.9E</td>
<td>Results of Robustness</td>
<td>130</td>
</tr>
<tr>
<td>Table 3.9F</td>
<td>Stability study results</td>
<td>131</td>
</tr>
</tbody>
</table>

**CHAPTER-4**

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 4.1</td>
<td>Variation of buffer concentration in mobile phase</td>
<td>143</td>
</tr>
<tr>
<td>Table 4.2</td>
<td>Variation of pH in the mobile phase</td>
<td>145</td>
</tr>
<tr>
<td>Table 4.3</td>
<td>Variation in column oven temperature</td>
<td>146</td>
</tr>
<tr>
<td>Table 4.4</td>
<td>Comparisons of results of analytical methods</td>
<td>149</td>
</tr>
<tr>
<td>Table</td>
<td>Description</td>
<td>Page</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
<td>------</td>
</tr>
<tr>
<td>Table 4.5</td>
<td>System suitability parameters for Zoledronic acid</td>
<td>149</td>
</tr>
<tr>
<td>Table 4.6</td>
<td>Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies.</td>
<td>150</td>
</tr>
<tr>
<td>Table 4.7</td>
<td>Results of Accuracy</td>
<td>151</td>
</tr>
</tbody>
</table>

**CHAPTER-5**

| Table 5.1 | Weighted linear regression of Zoledronic acid | 162 |
| Table 5.2 | Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies. | 163 |
| Table 5.3 | Results of Accuracy | 164 |

**CHAPTER-6**

| Table 6.1 | % Degradation products against their corresponding conditions, observed under forced degradation studies. | 174 |
| Table 6.2 | Results of Precision and Accuracy at LOQ level. | 178 |
| Table 6.3 | Results of Detector Response linearity. | 179 |
| Table 6.4 | System suitability parameters for Pemetrexed. | 180 |
| Table 6.5A | Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies for Pem-7. | 181 |
| Table 6.5B | Repeatability and Intermediate precision data evaluated through intra-day and inter-day studies for Pem-8. | 181 |
| Table 6.6A | Accuracy results for Pem-7 | 182 |
| Table 6.6B | Accuracy results for Pem-8 | 182 |
| Table 6.7 | Results of solution stability | 184 |
| Table 6.8A | Variation in flow rate | 185 |
| Table 6.8B | Variation in column temperature | 185 |
| Table 6.8C | Variation in gradient program | 186 |