# APPENDIX 1

**Caribbean Public Health Agency Drug Testing Laboratory- Jamaica (CARPHA-DTL)**  
Hope Gardens, Kingston 6

**SCOPE OF ACCREDITATION**  
Certificate Ref. No.: CPH033/LA/2017/CERT10

<table>
<thead>
<tr>
<th>Products/Materials Tested</th>
<th>Type of Tests</th>
<th>METHODS</th>
<th>EQUIPMENT (where appropriate)</th>
<th>REFERENCE RANGE</th>
<th>MEASUREMENT UNCERTAINTY</th>
</tr>
</thead>
</table>
| Pharmaceutical Finished Products (capsules, tablets, creams, ointments, suspensions, syrups, lotions) | High Performance Liquid Chromatography (HPLC)  
- Dissolution (with paddles)  
- Dissolution (with baskets)  
- Assay  
- Content Uniformity  
- Identification | USP General Chapter <621> Chromatography  
USP General Chapter <711> Dissolution  
BP Appendix XII B. Dissolution  
BP Appendix III D. Liquid Chromatography  
USP General Chapter <905> Uniformity of dosage units  
BP Appendix XII C. Consistency | HPLC Instruments  
Dissolution Units | As specified for each product in their individual monograph  
For example  
**Quantification:**  
USP Amoxicillin Capsules 90.0% to 120.0% of the stated amount  
**Identification:**  
USP Amoxicillin Capsules  
The retention time of the major peak of the Sample | $U_{\text{Dissolution}} = \pm 0.3$  
$U_{\text{Assay}} = \pm 0.5$  
$U_{\text{Content Uniformity}} = \pm 0.4$  
$U_{\text{Identification}} = \text{Not Applicable}$ |

USP – United States Pharmacopeia  
BP – British Pharmacopoeia
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<tbody>
<tr>
<td>Pharmaceutical Finished Products (capsules, tablets)</td>
<td>Disintegration</td>
<td>USP General Chapter &lt;701&gt; Disintegration&lt;br&gt;BP Appendix XII A. Disintegration</td>
<td>Disintegrator</td>
<td>solution corresponds to that of the Standard Solution as obtained in the Assay.</td>
<td>$U_{\text{disintegration}} = \pm 0.1$</td>
</tr>
</tbody>
</table>
| Pharmaceutical Finished Products (capsules, tablets, creams, ointments, suspensions, syrups, lotions) | Ultraviolet Visible Spectroscopy (UV/Vis) • Dissolution (with paddles) • Dissolution (with baskets) • Content Uniformity • Assay • Identification | USP General Chapter <851> Spectrophotometry and Light-Scattering-Fluorescence Spectroscopy<br>USP General Chapter <905> Uniformity of dosage units<br>USP General Chapter <711> Dissolution<br>BP Appendix II B. Ultraviolet and Visible Absorption Spectrophotometry<br>BP Appendix XII C. Consistency pf formulated preparations – | UV/VIS Spectrophotometer Dissolution Units | As specified for each product in their individual monograph. | $U_{\text{dissolution}} = \pm 0.5$
| | | | | For example **Quantification:** BP Paracetamol Tablets 95.0 to 105.0% of the stated amount | $U_{\text{assay}} = \pm 0.5$
| | | | | **Identification:** BP Furosemide Tablets The light absorption in the range 220 to 320 nm of the final solution obtained in the Assay exhibits two maxima at 228 nm and 271 nm. | $U_{\text{content uniformity}} = \pm 0.7$
<p>| | | | | <strong>Identification</strong> = Not Applicable | $U_{\text{identification}} = \text{Not Applicable}$ |</p>
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<tr>
<td>Pharmaceutical Finished Products (powder for injection, injections, creams, suspensions, syrups, lotions)</td>
<td>pH</td>
<td>Uniformity of Content&lt;br&gt;BP Appendix XII B. Dissolution</td>
<td>Orion pH Meters</td>
<td>As specified for each product in their individual monograph</td>
<td>$U_{\text{pH}} = \pm 0.04$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>USP General Chapter &lt;791&gt; pH&lt;br&gt;BP Appendix V L. Determination of pH Values</td>
<td></td>
<td>For example USP Carboplatin for injection Between 5.0 to 7.0 in a solution constituted as directed in the labelling, sterile water for injection being used.</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Finished Products (capsules, tablets, powders for injection)</td>
<td>Uniformity of weight</td>
<td>Uniformity of dosage units&lt;br&gt;BP Appendix XII C. Consistency of formulated preparations – Uniformity of Weight</td>
<td>Analytical Balances</td>
<td></td>
<td>$U_{\text{UNIFORMITY OF WEIGHT}} = \pm 0.1$</td>
</tr>
</tbody>
</table>