1.0 GENERAL INFORMATION

1.1 Introduction

The guidelines outlined below are provided to assist clients with the steps involved in sending samples to the laboratory for analysis. It is CARPHA Drug Testing Laboratory's goal to work with clients to protect the integrity of their samples and to provide timely analysis.

Daily hours of operation are between 8:30 a.m. and 4:30 p.m. Arrangements should be made to deliver samples within the hours of operation.

1.2 Laboratory Services

CARPHA DTL offers the following testing services:

1.2.1 Chemical & Physico-Chemical Analysis

- Disintegration
- Qualitative Identifications (colour reactions, precipitation reactions, etc)
- Dissolution
- Loss on Drying
- pH
- Water Content
- Uniformity of Dosage Units (mass, content)
- Titration
- Specific Gravity/Weight per mL
- Potentiometry
- Thin Layer Chromatography

1.2.2 Instrumental Analysis

- High Performance Liquid Chromatography
- Spectrophotometry (UV-Vis, FTIR)

1.2.3 Microbial Analysis

- Antibiotics-Microbial Assay (Cylinder Plate)
- Sterility
- Microbiological Examination on non-sterile products (microbial enumeration tests, absence of specific microorganisms)
1.2.4 **Standards**

The following procedures and standards serve as the basis for verification of pharmaceutical product quality:

- The British Pharmacopoeia (BP)
- The United States Pharmacopoeia and National Formulary (USP)
- Manufacturer’s monographs

1.3 **Request for Analysis**

1.3.1 Columns 1 to 3 on the Request for Analysis Form, FOR-CARPHA DTL-008-01, must be completed and forwarded to the laboratory for review.

1.3.2 **PRODUCTS ARE NOT TO BE SUBMITTED AT THIS STAGE.**

1.3.3 A technical review will be conducted to determine the tests the laboratory can perform.

1.3.4 Upon completion of the review, column 4 will be completed and the form returned to the client.

1.3.5 At this stage the client is requested to indicate acceptance of the proposed tests by completion of column 5. The form should then be returned to the laboratory.

1.3.6 Upon confirmation of acceptance, procurement of the necessary reference standard(s) and reagent(s) will be initiated. Application for the necessary import permits will also be initiated.

1.3.7 The client will then be notified to submit the sample(s) to the laboratory using CARPHA DTL Product Submission Form, FOR-CARPHA DTL-008-02.

1.3.8 For customs declaration purposes, the invoice accompanying the shipped products should have a minimal value on the items, and a clause/ statement explaining that the purpose of the shipment is not for resale or consumption but for testing and obtaining test results. All unused portions will be disposed of by this laboratory.

1.4 **Sample Submission**

1.4.1 Each sample submitted to the laboratory, **MUST** be accompanied by a completed CARPHA DTL Product Submission Form, FOR-CARPHA DTL-008-02.
2.0 MINIMUM QUANTITY OF SAMPLE REQUIRED FOR ANALYSIS

Please note:

Where the content of the drug per tablet is 5 mg or less, contact the laboratory.

2.1 COMPLETE ANALYSIS AS REQUIRED BY THE PHARMACOPOEIAS

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Number of Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets &amp; Capsules</td>
<td>100</td>
</tr>
<tr>
<td>Oral Solutions</td>
<td>5</td>
</tr>
<tr>
<td>Ointments &amp; Creams</td>
<td>5</td>
</tr>
<tr>
<td>(For tubes containing less than 5g or 5mL contact the Laboratory)</td>
<td></td>
</tr>
<tr>
<td>Sterile Products</td>
<td>30</td>
</tr>
</tbody>
</table>

2.1.2 REQUIREMENTS FOR INDIVIDUAL TESTS

1. Weight Variation
   This test is performed on tablets, capsules, solids in single unit containers and sterile solids for parenteral use where the average weight of contents is more than 40 mg. Thirty (30) units are required.

2. Assays
   If the sample is a tablet or a capsule and weight variation test is performed on it, no additional units are required. For all other types of samples (creams, parenteral solutions, etc.) the number of units required will depend upon the type of assay being performed.

3. Identification/ Related substances/ Breakdown products
   If the sample is a tablet or a capsule and weight variation test is performed on it, no additional units are required. For all other types of samples (creams, parenteral solutions, etc.) the number of units required will depend upon the method of analysis.

4. Dissolution and Disintegration
   These tests are performed on tablets and capsules. Twenty-four (24) units are required.

5. Uniformity of Content
   This test is performed on tablets and capsules according to the guidelines of the Pharmacopoeias. Thirty (30) units are required.

6. Microbial Limit/ Freedom from Pathogens Tests
These tests estimate the numbers of viable aerobic microorganisms present as well as determining whether the sample is free from designated microbial pathogens. For solids approximately 50 g are required. For other preparations approximately 50 mL are required.

7. **Efficacy of Antimicrobial Preservative**
This test demonstrates the effectiveness of any added antimicrobial preservative that has been added. It is applied to multiple dose products. A minimum of seven (7) containers are required.

8. **Sterility Tests**
These tests are performed on preparations or articles that are required to be sterile (e.g., opthalmic and parenteral preparations).

**BATCH SIZE UNKNOWN**

<table>
<thead>
<tr>
<th>Container content (mL)</th>
<th>No. of containers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10</td>
<td>30</td>
</tr>
<tr>
<td>10 to less than 50</td>
<td>30</td>
</tr>
<tr>
<td>50 to less than 100</td>
<td>30</td>
</tr>
<tr>
<td>50 to less than 100, intended for IV</td>
<td>20</td>
</tr>
<tr>
<td>100 to 500</td>
<td>20</td>
</tr>
<tr>
<td>Over 500</td>
<td>20</td>
</tr>
</tbody>
</table>

**BATCH SIZE KNOWN (GUIDELINES FOR MANUFACTURERS)**

<table>
<thead>
<tr>
<th>No. of items in the batch</th>
<th>No. of containers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parenteral preparations:</strong></td>
<td></td>
</tr>
<tr>
<td>100 or less</td>
<td>10% or 4 containers whichever is the greater</td>
</tr>
<tr>
<td>100 to 500</td>
<td>10</td>
</tr>
<tr>
<td>Over 500</td>
<td>2% or 30 containers, whichever is the less</td>
</tr>
<tr>
<td><strong>Eye/ other non-injectable preparations:</strong></td>
<td></td>
</tr>
</tbody>
</table>
200 or less | 5% or 2 containers whichever is the greater
More than 200 | 10

N.B. In order to validate the test for a preparation that has not been previously submitted, twice the number of containers given in the above table must be submitted.

3.0 Certificate of Analysis

3.1 On completion of testing a Certificate of Analysis of the test results will be prepared and issued. An advanced (scanned copy) will be sent to the client via email and the original will be sent to the postal address of the client.

If there are questions regarding laboratory services and policies, please call the Laboratory and staff will answer any questions.

Suggestions or comments for improvements to the Laboratory are encouraged and can be submitted to the laboratory by completion of the Customer Feedback Form.

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