Medicines Quality Control and Surveillance Department

Product Submission Guidelines
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 Department for analysis. It is CARPHA Medicines Quality Control Department (CARPHA MQCSD) goal to work with customers 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 Testing Services

CARPHA MQCSD 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)

1.2.4 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-MQCSD-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 Department can perform.

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

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

1.3.6 Upon confirmation of acceptance, the sample may be submitted to the Department. 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 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 Department.

1.4 Sample Submission

1.4.1 Each sample submitted to the Department, MUST be accompanied by a completed CARPHA MQCSD Product Submission Form, FOR-MQCSD-008-02. The customer must complete Sections 1 to 17. MQCSD completes the remaining sections.

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 Department.

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>
</tbody>
</table>

(For tubes containing less than 5g or 5mL contact the Department)
2.1.2 REQUIREMENTS FOR INDIVIDUAL TESTS

1. Weight Variation
   This test is performed on tablets, capsules and solids in single unit containers 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.

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 customer via email and the original will be sent to the postal address of the customer.

3.2 Certificates of Analysis for samples submitted for routine analysis are issued within 30 to 45 working days. Certificates of Analysis for samples submitted for the MQCSD post market surveillance programme are issued on the established schedule.

If there are questions regarding MQCSD’s services and policies, please call the Department and staff will answer any questions. Further information can also be found at on the CARPHA website at www.carpha.org under What we do – Medicines Quality Control and Surveillance Department.

Suggestions or comments for improvements to the Department are encouraged and can be submitted to the Department by completion of the Customer Feedback Form that is available on the website or can be requested from the Department.

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