

11. GUIDELINE FOR THE SUBMISSION OF PRODUCT SAMPLES FOR LABORATORY TESTING

The submission of sample for laboratory testing is as part of the registration process. This guideline consists of the general and specific requirements for the submission of samples to the Centre for Quality Control for laboratory testing. The general requirements define the condition of the samples to be submitted whereas the specific requirements illustrate the additional details needed according to the category of product.

The applicant is given a period of **14 working days** from the date of confirmed payment to send samples for laboratory testing. If the samples are not submitted within the specified time frame, the product registration application shall be tabled to the Authority for rejection.

The applicants shall comply with these requirements and failure to meet any of these requirements may cause rejection of the samples.

11.1 GENERAL REQUIREMENTS

- a) After the registration payment has been approved, applicants must make appointment with the Laboratory Services Unit for the submission of registration samples for laboratory testing.
- b) Requirements for samples:
 - i) A cover letter consisting of the following information should enclosed with every sample submission :
 - Name and reference no of product;
 - Name and address of holder;
 - Name, email address and contact number of authorized person;
 - ii) Samples submitted must be in their original packaging & labeling.
 - iii) Samples submitted must be from the same manufacturing premise as stated in the application for registration.
 - iv) Samples submitted must have an expiry date of least one (1) year from the date of submission and must be from the same batch number

- c) For imported products, applicants are required to submit the original import permit together with the samples for laboratory testing. The import permit will be issued by the Centre for Registration for natural product and Centre for Quality Control for pharmaceutical products. The applicant should ensure that the import permit is endorsed by the enforcement officer at the entry point.
- d) The payment voucher and approved payment application status should also be submitted together with the samples.

11.2 SPECIFIC REQUIREMENTS

11.2.1 NATURAL PRODUCTS

- a) Quantity of samples submitted must be:
 - i. a minimum of 6 separate containers of all dosage forms with total contents of not less than 200 g or 200 mL; OR
 - ii. a minimum of 60 pieces of plasters or patches with total of not less than 200g.
- b) Centre For Quality Control will conduct testing for Heavy Metals, Microbial Contamination Test, Disintegration Test, Uniformity Of Weight and screening for adulteration for the samples submitted.
- c) The result of the tested sample is final and there is no provision for appeal.

11.2.2 PHARMACEUTICAL PRODUCTS

(Upon request from NPCB)

- a) An official certificate of analysis and the recent shelf-life specification from the manufacturer for the same batch of sample must be submitted with the sample.
- b) Quantity of samples submitted must be in accordance with the quantity requested.

- c) Other materials such as HPLC columns, reagents, etc must be submitted when requested.
- d) Reference standards are required to be submitted along with the pharmaceutical products. Requirements for these reference standards are as follows:
 - i) The type & quantity of reference standards submitted must be in accordance with the type & quantity requested;
 - ii) Reference standards submitted must have an expiry date of least one (1) year from the date of submission. In special situations, an expiry date of not less than six (6) months can be accepted;
 - iii) All reference standards must be accompanied by an official certificate of analysis for the same batch with the stated purity (as is, dried, anhydrous etc.) and all other relevant information (water content, loss on drying etc.);
 - iv) All reference standards must be properly labeled with name, batch number, purity and expiry date;
 - v) All reference standards must be submitted in small sealed air-tight amber glass containers.