

## 2 How to submit your application

Facilities are not allowed to sell for the public any compounded/mixed preparation unless it has been approved and priced by NHRA; and to secure NHRA's approval, the preparation facility should submit an application for the designated NHRA PPR department staff via email, with the following requirements:

1. Proposed compounded/mixed preparation list, in a tabulated Microsoft Excel sheet format, containing at least the below information:
    - a. Compounded/Mixed preparation name.
    - b. Compounded/Mixed preparation usage/indication.
    - c. Compounded/Mixed preparation total weight/volume.
    - d. Active ingredients/products names, and any excipients added and its concentrations/weights/volumes.
    - e. Cost of each active ingredient/product and any excipients added as per the used concentration/weight/volume.
    - f. Proposed compounded/mixed preparation container type.
    - g. Proposed compounded/mixed preparation container cost.
    - h. Total cost of the proposed compounded/mixed preparation.
    - i. Preparation fee/profit margin.
    - j. Final proposed public retail price.
  2. Copy of the proposed compounded/mixed preparation reference (e.g.: USP, BP, Ph. Eur...etc.).
  3. Copy of the active ingredients purchasing invoices.
  4. In case of imported active ingredients, copy of NHRA's approval for the importation is required.
  5. Proposed label artwork: Labelling Requirements
- Any compounded/mixed preparation should have its approved label before selling to the public; and the below are the minimum labelling requirements for approval:
1. Compounded/Mixed preparation name.
  2. Active ingredients names and its concentrations/weights/volumes.
  3. Preparation date.
  4. Expiry date (should not exceed 90 days from the preparation date) or as per the reference used.

## 1 Preparation facility

Preparation facility should be approved by NHRA, as per the requirements and conditions, before submitting the proposed compounded/mixed preparations for NHRA's final approval.



## 3 Final Approval

The designated NHRA PPR department staff will assess the received applications as per the above requirements and conditions, and in case of any deficiency, the applicant will receive a notification with the required corrective actions or missed documents.

For complete and complying applications, applicant will receive an approval email from the designated NHRA PPR department staff, containing the approved compounding/mixing details and public retail prices, to start the compounding/mixing procedures. Any proposed change on the approved compounding/mixing preparations (including volumes, weights, concentrations, container type, label design...etc.) should be submitted for NHRA's approval before selling to the public.

