1 Request an Appointment

In order to submit new application, the applicant must request an appointment from the concerned staff in PPR department by email. Appointments are assigned on a first-come basis.

2 Submit your application

- **On the appointment day NHRA staff will check the file to make sure all the requested documents are available, only valid applications will be accepted.**
- **List of documentations required for Active Pharmaceutical Ingredients (API) / Excipient:**

1. Cover letter from the applicant with the information about the imported material and purpose of importing.
2. Copy of valid GMP certificate for the API manufacturing site.
3. Copy of valid manufacturing license for the e API/Excipient manufacturing site.
4. Letter of access from the API/Excipient manufacturing site.
5. Active substance master file on CD.
6. Copy of certificate of analysis (COA) for API/Excipient.
7. Alcohol content declaration.
8. Porcine content declaration.
9. TSE free declaration or certificate of suitability.
10. List of countries the API/Excipient is exported.

- **List of documentation required for bulk product (semi-finished formulation):**

1. Cover letter from the applicant.
2. Copy of valid GMP certificate for the manufacturing site.
3. Copy of NHRA site registration certificate.
4. Alcohol and pork content declaration.
5. Composition Certificate.
6. Certificate of Analysis.

3 Assessment & Approval

- During assessment, in cases where queries arise, a request for further information will be sent to the applicant.
- Approval is valid for 3 years.
- NHRA reserves the right to cancel or withdraw the approval for any raw material/bulk (semi-finished formulation) if found non-compliant during its lifecycle after approval.

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