

1 Preliminary Approval

- The applicant is required to submit an official letter addressed to NHRA CEO, detailing the intended production lines and brief of manufacturing site. A letter of no objection will be issued by the CEO's office.
- The Applicant apply through Sijilat.bh, for Initial application for approval of pharmaceutical manufacturing site license including all documents as per the application form available on NHRA website and pay the initial application fees:
 1. Application form for Initial Approval of Pharmaceutical Manufacturing Site.
 2. Copy of CPR & Passport of (owner and Partner/s).
 3. Copy of tenancy agreement or the owner contract.
 4. Manufacturing site layout/design.
- NHRA PPR inspect the site for construction approval.
- Upon successful inspection, applicant pay the initial fees 5000BD.
- A pre-approval letter signed by NHRA CEO will be issued to initiate construction of the manufacturing site.

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2 Procedure for Local Pharmaceutical Manufacturing Site Licensing

- On completion of construction of the manufacturing site, the applicant shall submit the application through Sijilat including all listed documents in the application form available on NHRA website:
 1. Application form for Approval of Pharmaceutical Manufacturing Site License.
 2. Copy of the initial approval.
 3. List of medicines and pharmaceutical products to be manufactured or packaged, and list of raw materials suppliers.
 4. Copy of the site master file (SMF).
- PPR-NHRA inspect the site after construction completion.
- Upon successful inspection, Applicant install machinery.
- Upon Installation of the machinery by the applicant, NHRA PPR shall conduct inspection.
- Upon successful inspection, the Applicant pays the licensing fees 5000BD/year, & after payment completion, NHRA shall grant Manufacturing License valid for 3 years.

3 Post issuance of Manufacturing License

- PPR-NHRA inspect the site after production of qualification/validation batch and displaying successful stability batches study.
- NHRA shall grant GMP certificate valid for 3 years.

