nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

# Pharmaceutical Manufacturer Licensing Procedure

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

**May 2019**

**Version 1.4**

## 1. Introduction

This document is meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. The document also provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent and effective.
Local pharmaceutical manufacturing site licensing is done through PPR department in NHRA.

This procedure has been developed to assist establishments/manufacture in the preparation and submission of applications for Local pharmaceutical manufacturing site licensing in the Kingdom of Bahrain.

It should be noted that the NHRA has the right to request any information and data within the context of this procedure.

This document should be read in conjunction with other applicable guideline documents.

## 2. Local Pharmaceutical Manufacturing Site

To initiate construction of a manufacturing site prior approval from ministry of industry and commerce, from National Health Regulatory Authority (NHRA) and from the environment control directorate is mandatory.

The manufacturer/establishment should submit an online application to the ministry of industry & commerce by logging on their website www.sijiat.bh and follow the required procedure.

The manufacturing site should be in an area, away from the source of pollution, gases, vapors, inflammable chemicals and residential area. The factory should be designed as per the international good manufacturing practices (GMP).

Pharmaceutical manufactures should note that they are responsible to adhere to the cGMP guidelines and consecutively to medicines quality, efficacy and safety throughout its life cycle. With further advancements in technology the manufacturing site may upgrade to meet the state of the art technology, it is the manufactures responsibility to inform NHRA when these changes occur as per the current guidelines.

The responsibilities include:

1. To ensure that all of the information given in the application form and supporting documents are true and valid.

2. To notify NHRA and seek approval for any change in the manufacturing site.
3. Send prior notification to NHRA in case where the manufacturing site is preparing for an inspection with regulatory agency other than NHRA. NHRA shall be a part of this inspection.
4. The manufacturer is required to send NHRA a copy of the above Inspection report.
5. To respond to NHRA queries or requests for more data for review, within the timelines.

Failure to comply with the above shall render the pharmaceutical manufacturing site license cancelled. Thus, NHRA reserves the right to suspended or withdraw the registration license of the pharmaceutical manufacturing site anytime during the production lifecycle, if found non-compliant.

Pharmaceutical manufacturing site license is valid for 3 years. The GMP certificate issued by NHRA upon successful completion of the GMP inspection is valid for 3 years.

## 3. Procedure for Local Pharmaceutical Manufacturing Site Licensing

The applicant is required to submit an official letter addressed to CEO NHRA, detailing the intended production lines and brief of manufacturing site. A no objection letter will be issued by the CEO's office.

Upon approval from the Ministry of industry and commerce the application will be automatically transferred to NHRA for further assessment. Following steps are to be followed.

### 3.1. Initial application for approval of Pharmaceutical manufacturing site

Applicants should prepare for an initial approval application for manufacturing site license including all documents listed in the application form (Annex I); this should be signed and stamped by the owner/general manger. An initial application fee is to be paid by the applicant.

Please note that for each application the most up to date versions of these forms should be downloaded directly from NHRA website.

Following conditions should be meet prior to filling this application:

1. Obtain approval from the ministry of industry and commerce.
2. Obtain approval from the environment control directorate.
3. Obtain approval from the municipality.
4. The manufacturing site should be in an area, away from the sources of pollution, gases, vapor, inflammable chemicals and residential area.
5. The factory should be designed as the international good manufacturing practices (GMP).

The proposed manufacturing site design/layout should be approved by NHRA.

The submission of the application for initial approval of pharmaceutical manufacturing site license prompts an inspection by NHRA.

Upon successful inspection NHRA shall issue a pre-approval letter signed by NHRA CEO to initiate construction of the manufacturing site. The applicant is required to pay fees per NHRA approved price list.

## Pharmaceutical manufacturing site license application

On completion of construction of manufacturing site, the manufacturer/establishment shall seek an appointment for submitting the application including all listed documents in Application form for Pharmaceutical manufacturing site license (Annex II); this form should be signed and stamped by the qualified personal mentioned in the form.

Following conditions should be meet prior to filling of this application:

1. Obtain the permit from civil defense.
2. The manufacturer recruit responsible person for quality control before the production start should have Bachelor degree in Pharmaceutical Science/chemist and should have a valid NHRA license.
3. Recruit general manufacturing manager and production manager should have Bachelor degree in Pharmaceutical Science and should have a valid NHRA license.

On receipt of the application form of pharmaceutical manufacturing site license the following step shall be followed:

1. NHRA shall conduct an inspection of the manufacturing site post completion of construction.
2. Upon Installation of the machinery, NHRA shall conduct inspection.
3. Upon successful inspection and before commencing production of the qualification/validation batches NHRA shall grant Manufacturing License.

The manufacturing license is valid for 3 years. The Applicant is required to pay the fees per NHRA approved price list.

## 4. Post issuance of Manufacturing License

Upon production of qualification/validation batch and displaying successful stability batches study, an inspection by NHRA is mandated. After which NHRA shall issue GMP certificate.

Any change in the manufacturing site shall be approved by NHRA prior to implementation.

Note:

1. Application fee shall be levied as per NHRA approved price list.
2. Manufacturing facility licensed as secondary packaging and /or batch releaser must ensure the establishment of complete production activities upon completion of 2 years from the manufacturing licensing date.

## Annex I

## Application for Initial Approval of Pharmaceutical Manufacturing Site

| **Owner Information** | | |
|---|---|---|
| ○ Establishment ○ Manufacturer | | |
| Establishment / Manufacturer Name: | | |
| Establishment / Manufacturer Nationality: | | |
| C R Number: | | |
| Expiry date : | | |
| **Establishment / Manufacturer Address** | | |
| City: | | |
| Area/District: | | |
| Building Number: | | |
| Block Number: | Road number: | |
| Phone: | | |
| Extension: | | |
| Fax: | | |
| Email: | | |
| Mailing Address: | | |
| **Manufacturer Location** | | |
| Manager Name: | | |
| City: | | |
| Area/District: | | |
| Building Number: | | |
| Block Number: | Road number: | |

| **Manufacturing Activities** |
| --- |
| ☐ Primary Packaging |
| ☐ Secondary Packaging |
| ☐ Finished Products Manufacturing |
| ☐ Active Pharmaceutical Ingredients Manufacturing |
| ☐ Others (Specify) |
| **Product Type** |
| ☐ Medicines |
| ☐ Health Products |
| ☐ Functional Foods |
| **Production Lines** |
| |
| **Delegated person to follow up with NHRA** |
| Contact Name : |
| CPR Number: |
| Phone: |
| Extension: |
| Mobile: |

| **Owner Commitment** |
| --- |
| This form has been filled by my knowledge with complete and correct information. Also, all attached documents are stamped by company's stamp and considered as an official copy. I take the extreme responsibility for any forgery or incorrect information on these documents |
| I undertake to update any changes in the current information |
| I will not manufacture or market any product unless it is registered by NHRA & have a certificate of Good Manufacturing Practices (GMP) |
| I have read all terms and conditions of the Kingdom of Bahrain law # 15 of 2007 for Narcotics and Psychotropic Substances and I undertake to follow all its content and regulations followed, also I undertake to follow any regulation issued by NHRA in future |
| I have read all terms and conditions of the Kingdom of Bahrain law # 18 of 1997 for Regulation of Pharmacy and I undertake to follow all its content and regulations , also I undertake to follow any regulation issued by NHRA in future. |
| Name :<br><br>Date:<br><br>Owner / General Manager (For manufacturer) signature :<br><br><br><br><br>Stamp: |

| Documents/and conditions needed for initial approval of pharmaceutical manufacturing site |
|---|
| **Conditions:** |
| 1. Obtain approval from the ministry of industry and commerce. |
| 2. Obtain approval from the environment control directorate. |
| 3. Obtain approval from municipality. |
| 4. The manufacturing site should be in an area , away from the sources of pollution, gases, vapour, inflammable chemicals and residential area. |
| 5. The factory design should be as per the international good manufacturing practices (GMP). |
| **Documents:** |
| 1. Submit letter to chief executive officer of NHRA to obtain initial approval for the manufacturing site. |
| 2. Copy of CR. |
| 3. Copy of tenancy agreement or the owner contract. |
| 4. Copy of approval from the ministry of industry and commerce. |
| 5. Copy of approval from municipality. |
| 6. Manufacturing site layout/design. |
| N.B all documents should be valid. |

## Annex II

## Application for Approval of Pharmaceutical Manufacturing Site License

| **Manufacture Information** | | |
|---|---|---|
| Manufacture Name : | | |
| Initial Approval Reference : | | |
| C R Number: | | |
| Expiry date: | | |
| **Manufacturing Address** | | |
| City: | | |
| Area/District: | | |
| Building Number: | | |
| Block Number: | Road number: | |
| Phone: | | |
| Extension: | | |
| Fax: | | |
| Email: | | |
| Mailing Address: | | |
| **Manufacture activities** | | |
| ☐ Primary Packaging | | |
| ☐ Secondary Packaging | | |
| ☐ Finished Products Manufacturing | | |
| ☐ Active Pharmaceutical ingredients Manufacturing | | |
| ☐ Others ( Specify) | | |
| **Product Type** | | |
| ☐ Medicine | | |
| ☐ Health Products | | |
| ☐ Functional Foods | | |

| **Production Lines** | | |
|---|---|---|
| | | |
| **Owner Information** | | |
| ○ Establishment | ◉ Manufacturer | |
| Establishment / Manufacturer Name: | | |
| Establishment / Manufacturer Nationality: | | |
| **Address** | | |
| City: | | |
| Area/District: | | |
| Building Number: | | |
| Block Number: | Road number: | |
| Phone: | | |
| Extension: | | |
| Fax: | | |
| Email: | | |
| Mailing Address: | | |
| **Production Manager Information** | | |
| Name: | | |
| CPR Number: | | |
| Expiry date: | | |
| NHRA Pharmacist License Number: | | |
| Expiry date: | | |
| Mobile : | | |
| Email: | | |

| **Quality Control Manager Information** |
|---|
| Name: |
| CPR Number: |
| Expiry date: |
| NHRA Pharmacist License Number: |
| Expiry date: |
| Mobile : |
| Email: |
| **Are there any narcotic or controlled drugs?** |
| ○ Yes ○ No |
| Name of person in charge: |
| CPR Number: |
| Expiry date: |
| NHRA Pharmacist License Number: |
| Expiry date: |
| **The official address for receiving the official letter and memos from NHRA** |
| Fax No: |
| Email : |
| Mailing Address: |
| **Delegated person to follow up with NHRA** |
| Contact Name : |
| CPR number: |
| Phone: |
| Extension: |
| Mobile: |

| **Quality Control Manager Commitment** |
| --- |
| I have the full responsibility for all released batches and applying good manufacturing practices |
| In case of termination of my contract with the establishment/ manufacturer for any reason I undertake to inform NHRA within thirty days start by last working day |
| I have read all terms and conditions of the Kingdom of Bahrain law # 18 of 1997 for Regulation of Pharmacy and I undertake to follow all its content and regulations , also I undertake to follow any regulation issued by NHRA in future. |
| Name :<br><br>Date:<br><br>Quality Control Manager signature :<br><br>Stamp: |

| **Production Manager Commitment** |
| --- |
| In case of termination of my contract with the establishment/ manufacturer for any reason I undertake to inform NHRA within thirty days start by last working day |
| I have read all terms and conditions of the Kingdom of Bahrain law # 18 of 1997 for Regulation of Pharmacy and I undertake to follow all its content and regulations , also I undertake to follow any regulation issued by NHRA in future. |
| Name :<br><br>Date:<br><br>Production Manager signature :<br><br><br><br>Stamp: |

| **Person in charge of Narcotics & Controlled Drug Commitment** |
| --- |
| In case of termination of my contract with the establishment/ manufacturer for any reason I undertake to inform NHRA within thirty days start by last working day |
| I have read all terms and conditions of the Kingdom of Bahrain law # 15 of 2007 for Narcotics and Psychotropic Substances and I undertake to follow all its content and regulations followed, also I undertake to follow any regulation issued by NHRA in future. |
| I have read all terms and conditions of the Kingdom of Bahrain law # 18 of 1997 for Regulation of Pharmacy and I undertake to follow all its content and regulations , also I undertake to follow any regulation issued by NHRA in future. |
| Name :<br><br>Date:<br><br>Person in charge signature :<br><br><br><br><br>Stamp: |

| **Owner Commitment** |
| --- |
| This form has been filled by my knowledge with complete and correct information. Also, all attached documents are stamped by company ‘s stamp and considered as an official copy. I take the extreme responsibility for any forgery or incorrect information on these documents |
| I undertake to update any changes in the current information |
| I will not manufacture or market any product unless it is registered by NHRA & have a certificate of Good Manufacturing Practices (GMP) |
| I have read all terms and conditions of the Kingdom of Bahrain law # 15 of 2007 for Narcotics and Psychotropic Substances and I undertake to follow all its content and regulations followed, also I undertake to follow any regulation issued by NHRA in future. |
| I have read all terms and conditions of the Kingdom of Bahrain law # 18 of 1997 for Regulation of Pharmacy and I undertake to follow all its content and regulations , also I undertake to follow any regulation issued by NHRA in future. |
| Name :<br><br>Date:<br><br>Owner / General Manager (For manufacturers) signature :<br><br><br><br><br>Stamp: |

| **Documents/and conditions needed for Application for Pharmaceutical Manufacturing License** |
|---|
| **Conditions:** |
| 1. Submit an official request for the chief pharmaceutical product registration of NHRA to obtain the license. |
| 2.Obtain the permit of civil defense. |
| 3.The manufacture recruit responsible person for quality control before the production start, should have the following qualifications:<br>o Bachelor degree in Pharmaceutical science/ Chemist<br>o Valid NHRA license. |
| 4.Recruit general manufacturing manager and production manager with the following qualifications:<br>o Bachelor degree in Pharmaceutical science.<br>o Valid NHRA license. |
| **Documents:** |
| 1.Request form for registration of manufacturer for pharmaceutical product |
| 2.Copy of the initial approval. |
| 3.Copy of civil defense permit. |
| 4.Copy of CR from ministry of Industry and commerce. |
| 5.Copy of approval from Municipal. |
| 6.Copy of approval from environment control directorate. |
| 7.Copy of approval of the manufacturing site layout/design. |
| 8.Copy of the site master file (SMF). |
| N.B all documents should be valid. |