# SUDAN
# PHARMA MARKET
# &
# REGULATORY PROFILE

**Pharmaceuticals Export Promotion Council of India**

(Set up by Ministry of Commerce & Industry, Government of India)

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# DEMOGRAPHY

| Sr. No. | Parameter | Description |
|---|---|---|
| 1 | Region | AFRICA |
| 2 | Country | SUDAN |
| 3 | Capital | Khartoum |
| 4 | Population | 45,561,556 (July 2020 est.) |
| 5 | Population growth rate (%) | 2.69% (2020 est.) |
| 6 | GDP (purchasing power parity) | $177.4 billion (2017 est.) |
| 7 | GDP - real growth rate (%) | 1.4% (2017 est.) |
| 8 | GDP - per capita (PPP) | $4,300 (2017 est.) |
| 9 | Epidemiology | HIV bacterial and Protozoal diarrhea, hepatitis A and E, and typhoid fever, malaria, dengue fever, and Rift Valley fever schistosomiasis |
| 10 | Population below poverty line | 46.5% (2009 est.) |
| 11 | Age structure (%) | **0-14 years:** 42.01%<br>**15-24 years:** 20.94%<br>**25-54 years:** 29.89%<br>**55-64 years:** 4.13%<br>**65 years and over:** 3.03% |
| Source: CIA World Fact Book updated to July 2020 | | |

# MARKET REPORT

## INTRODUCTION

Sudan's currency devaluation has led to the shortage of a number of medicines, with some products also becoming completely unavailable for sale in the country. Sudan's industry needs to import active pharmaceutical ingredients (APIs) which makes market extremely vulnerable to currency fluctuations and external headwinds. Donations are likely to play an important role in the short to medium term, as the industry and operational risks continue to undermine any major pharmaceutical company activity.

### Strengths

- Compared to many Sub-Saharan African pharmaceutical markets, Sudan's pharmaceutical market is large in value terms, albeit mainly due to its vast population.
- Strategic position favors medicine distribution between its neighboring peers in North Africa and Sub Saharan Africa.
- Relatively robust regulatory system, in comparison with its peers

### Weaknesses

- Low government and out-of-pocket per capita health expenditure.
- Weak intellectual property laws.
- Sudan and South Sudan are not members of the World Trade Organization.

### Opportunities

- A large population is advantageous for long-term pharmaceutical demand.
- Investment from countries such as Nigeria, Turkey and Qatar should help raise the quality of healthcare provision and infrastructure.
- There is a growing presence of foreign generic drug makers, including Indian and Middle Eastern pharmaceutical companies

## Market

The outlook for Sudan's pharmaceutical market will continue to be affected by the prevailing economic and political environment. Sudan may not be on the radar of innovative Pharma companies in the next Five to seven years, especially given the recent currency devaluation that has severely dented foreign currency market values.

In 2017, pharmaceutical expenditure is put at USD533mn, accounting for 8% of the country's Healthcare expenditure or USD13 per capita. Exchange rate fluctuations will continue to negatively impact market growth in USD terms. Indeed, in 2018, the market will be worth USD184mn.

The devaluation of the Sudanese pound in H118is the reason behind the huge negative growth in

USD terms. This undermines the overall size of the market and has implications on Sudan's domestic pharmaceutical manufacturers. Inflationary pressures will push up pharmaceutical

import costs and this poses a significant risk to domestic drug makers as they rely raw material imports.

Forecast show that by 2022 market may reach a $ 176 million with a negative cagr of 19.9%. Currently, almost half the population is below the poverty line indicating a lopsided income distribution. Plans are underway to improve employment and other modes of increasing purchase capacity. This may take a while. Generics in these circumstances have better opportunities.

## Epidemiology

The burden of disease in Sudan and South Sudan is split fairly evenly between communicable and non-communicable diseases.

According to UNAIDS, the number of people living with **HIV** in Sudan is 56,000, corresponding to a prevalence rate of 0.3% in adults aged between 15 and 49. In South Sudan, there are an estimated 180,000 HIV sufferers, which corresponds to a prevalence rate of 2.5%.

According to Globocan, the number of new cases of **cancer** in Sudan will increase from 20,355 in 2012 to 36,037 in 2030. Over the same time period, in South Sudan, this figure will increase from 8,688 to 15,462.Many cases are often undiagnosed or misdiagnosed, which is partly due to inadequate healthcare infrastructure and partly due to the widespread lack of awareness regarding the disease. According to Globocan, prostate cancer is the most common cancer in males, followed by Non-Hodgkin lymphoma, liver cancer and leukaemia. Breast cancer is the most frequent cancer in females, followed by cervical, ovarian and oesophagus cancer. According to the International Diabetes Federation (IDF), there were 1.4mn cases of diabetes in Sudan and South Sudan in 2015, with diabetes-related deaths reaching a value of over 22,000.

Neuropsychiatric disorders such as depression, epilepsy and Alzheimer's disease are causing an increasing burden in Sudan and South Sudan.

## Local Industry

Currently, no major multinational drug makers produce medicines locally, instead preferring to supply the market via imports. GlaxoSmithKline, Roche and Novartis are all present through partnerships with local distributors. Hikma produces locally, with Saudi drug maker Tabuk also having a manufacturing presence. The leading Sudanese companies are Liliam Pharmaceutical Industries, Ami Pharma, Azal Pharmaceuticals and Blue Nile Pharmaceutical, with domestic producers supplying a lower proportion of the market by value. There is also a strong presence of foreign generic drugmakers, including Indian companies Taj Pharma, Gujarat Terce Laboratories and Jenburkt Pharmaceuticals.

### Domestic Industry

There is a relatively significant domestic pharmaceutical industry in both Sudan and South Sudan, with 24 licensed pharmaceutical manufacturers operating in the market (according to latest available data from the Department of Production at the Ministry of Industry). However,

the basic capabilities of the local drug makers will make it difficult to achieve self-sufficiency and the supply of more sophisticated medicines will remain mandatory by imports. This current lack of capacity is highlighted by the fact that only 729 of the 5,000-plus registered pharmaceuticals are produced locally.

## Export Statistics

### India's exports to Sudan (mn USD)

| Category | 2018-19 | 2019-20 | % Growth |
|---|---|---|---|
| Ayush & Herbals | 0.65 | 1.23 | 88.46 |
| Bulk Drugs & Drug Intermediates | 17.20 | 18.53 | 7.73 |
| Drugs formulations & Biologicals | 48.05 | 53.38 | 11.10 |
| Surgicals | 1.71 | 2.16 | 25.88 |
| **Grand Total** | 68.46 | 76.90 | 12.32 |

Note on Market Report:

Since there is no updated market information available we have offered the old report developed in 2018 with the updated export values. .

# REGULATORY AND REGISTRATION REQUIREMENTS

- Regulatory Authority : National Medicines and Poisons Board
- Website of regulatory Authority : http://www.nmpb.gov.sd/
- Fees for Drug Registration :
- Normal time taken for registration : 12 Months
- Registration Requirement [Dossier Format] : CTD
- Whether plant inspection is mandatory : Yes
- Validity of Registration : 5 Years

## Regulatory

Sudan has a semi-autonomous medicines regulatory authority, which was originally part of the Ministry of Health and is now known as the National Medicines and Poisons Board. South Sudan is establishing its own regulatory regime through its Ministry of Health.

In comparison to its regional peers, Sudan's regulatory regime is relatively well established. However, the fact that Sudan and South Sudan are not members of the World Trade Organization

(WTO) is a considerable area of concern for innovative drug makers.

All pharmaceutical products require marketing authorization in Sudan, of which there are explicit criteria for applicants. There is a 12-month time limit for assessing a marketing authorization and all medicines facilities must also be approved for licensing from the regulatory authority. Technically, there is a requirement for manufacturers to comply with good manufacturing practice (GMP), but the government has not published a locally applicable document. Inspectors are legally permitted to inspect premises where pharmaceuticals are produced or packaged. Equally, imports must be licensed by the authorities.

No legal provisions exist in the Sudanese Medicines and Poisons Act requiring Pharmacovigilance activities as part of the medicines regulatory authority (MRA) mandate. The marketing authorization holder does not have to continuously monitor the safety of their products and report to the MRA.

The national medicines and poisons board do stress the importance of Pharmacovigilance activity, and a specific Pharmacovigilance center linked to the MRA exists in Sudan. A laboratory exists in Sudan for the purpose of quality control testing, however the results are not made publically available.

## About the NMPB

### Introduction:

The supervisory work on pharmaceutical preparations in Sudan began virtually after independence since the 1960s, when the first law, the Pharmacy and Toxicology Law, was prepared in the year 1963 AD, by which it was entrusted with the task of enforcing it to the Federal Ministry of Health represented by the General Administration of Pharmacy and its departments in the various regions to view the supervisory work and license Pharmaceutical establishments in accordance with that law, and the situation remained unchanged until the law was amended in the year 2001 AD, but the supervisory role continued within the direct responsibilities and powers of the Federal Ministry of Health through the General Administration of Pharmacy and the departments Affiliate state.

The Federal Council for Pharmacy and Toxicology was established in the year 2001 AD under the Pharmacy and Toxicology Law for the year 2001 AD, and it remained operating under the umbrella of the General Administration of the Federal Pharmacy until the year 2007 AD and since that year it has been under the supervision of the Federal Minister of Health, and includes in its membership representatives of institutions and bodies related to drug control (human And veterinary) in addition to other medical products, and to have a general secretariat with direct executive tasks and independent technical, administrative and financial powers, and in 2009 the law was amended to become the Medicines Law And toxins for the year 2009 AD and it is currently applied

According to the Drugs and Toxins Act of 2009 Article 6 (6) The National Council for Medicines and Toxins is the national authority competent to set specifications, controls and conditions for import, manufacture, control, storage, pricing, deportation, and the use of medicines, cosmetics, and all medical supplies and pharmaceutical preparations according to approved specifications.

### Tasks and functions:

A. Setting drug policies by manufacturing, importing, and distributing, and controlling the circulation and reception of drugs, drugs, medical supplies cosmetics, toxins, and narcotic drugs in cooperation with the relevant authorities in addition to the council's powers and competences, which are mentioned in the Drugs and Poisons Act of 2009, which are summarized as follows:

1. Approving reference laboratories and laying the foundations, controls and conditions necessary for licensing drug depots, pharmaceutical laboratories, drug factories, serum laboratories, veterinary vaccines and drug information offices.
**2.** Registration of medicines, pharmaceutical preparations, cosmetics, medical supplies and toxins, and specification of registration requirements.
3. Laying down the systems, controls and conditions necessary for the pharmaceutical establishment to perform the work licensed for it and continue to do the work.
4. Laying down the systems, controls and conditions necessary for the management of pharmaceutical facilities.

5. Registration of foreign pharmaceutical and medical supplies companies, their branches or both approved according to the controls and conditions determined by a decision from him.
6. Licensing to conduct drug trials on humans or animals after the license applicant fulfills the conditions set forth in Article 22 and is committed to all the conditions, controls and rules that the Council determines to conduct drug trials on humans and animals.
7. Setting the conditions for registering medicines, pharmaceuticals, cosmetics and medical supplies, which include observing need, safety, effectiveness, price, quality, consumer protection, the duration and renewal of registration, and fees to be paid.
8. Determine a specific type of medicine or pharmaceutical preparations and compel the owner of the warehouse or the representative of the producing company to import it whenever he deems it necessary to have that drug or pharmaceutical preparation in the country.
9. Obliging the pharmaceutical factories inside Sudan to produce any kind of drugs produced for them, as necessary.
10. Approve the export of medicines and pharmaceutical products abroad.
11. Laying the foundations and controls for keeping records of incoming and outgoing medicines and pharmaceutical preparations in the drugstore.
12. Regulating the processes of drug production, control, quality control and distribution.
13. Prepare a list of toxins, publish it in the Official Gazette, and amend it from time to time.
14. Form any temporary or permanent committees to help him perform his duties and define its terms of reference.
15. Adopting coordination policies with the relevant authorities.
16. Approving the organizational and functional structure of the General Secretariat.
17. Any other authorities necessary to implement the provisions of this law.

**B. Article (10) of the same law stipulates that the Council shall have a General Secretariat headed by the Secretary General, whose terms of reference are as follows**

1. Follow up the implementation of the council's decisions.
2. Assuming the executive, administrative, technical, and financial responsibility of the Council.
3. Preparing the council's agenda under the supervision of the council's president and keeping correspondence related to those works.
4. Keep the meeting records and present it to the members.
5. Send the council's decisions and recommendations to the competent authorities and inform the council of what has been implemented.
6. Maintaining the council's seal and using it in the manner determined by the regulations.

**Vision:**
Excellence in the field of control over medicines and pharmaceuticals
Pharmaceutical, medical devices and supplies
Cosmetics regionally and globally

**The message:**
Protecting public health by building a system Control to ensure safety, effectiveness and quality
Medication, pharmaceuticals and lotions Beauty and efficiency of medical devices and supplies
Based on scientific foundations to enhance cooperation with all partners

## Requirements for the registration of Foreign Plant

**A. General Requirements:**

1. The application form should be filled by the applicant
2. Any required Document certificate in language rather than English or Arabic should submit a translation from authorized body approved by NMPB.

**B. Specific Requirements**

**1. Requirement(s) for registration of foreign plant for human and veterinary medicine:**

1. A valid copy of manufacturing license issued by the competent authority in the country of origin.
2. A valid copy of GMP certificate issued by the competent authority in country of origin.
3. Update Site Master File.

**2. Requirement(s) for registration of foreign plant for dietary supplement and heath product:**

1. A valid copy of manufacturing license issued by the competent authority in the country of origin.
2. A valid copy of GMP certificate issued by the competent authority in country of origin or ISO 22000 or HACCP certificate.

**3. Requirement(s) for registration of foreign plant for cosmetic product:**

1. A valid copy of manufacturing license issued by the competent authority in the country of origin.
2. A valid copy of GMP certificate issued by the health authority in country of origin or ISO 22716.
3. Free sale certificate for a cosmetic product issued from competent authority in the country of origin.

**4. Requirement(s) for registration of foreign plant for medical device product:**

1. A valid copy of manufacturing license issued by the competent authority in the country of origin (except European countries, USA, Canada, Australia).
2. A valid copy of GMP certificate issued by the health authority in country of origin or ISO 13485.
3. Attach CE Certificate as supportive
4. Document for European countries.

http://www.nmpb.gov.sd/en/drug_hu_forgin.php?num=4

## Requirements for the registration of Human medicines

**A. General Requirements:**

1. The manufacturing plants should be registered within the NMPB.
2. The pharmaceutical product with the same specification should be registered and freely sold in the country of origin and if not please give justifications.
3. The application form should be filled by the applicant.
4. The prescribed fees should be paid.
5. All documents should be in English.

**B. Specific Requirements:**

**1. Certificate of Pharmaceutical Product (CPP):**

- As WHO format (or at least containing the same information).
- Should be valid and issued by the health authority in the exporting country and authenticated by Sudan Ministry of Foreign Affairs.
- The composition formula in (CPP) should show the active and inactive ingredients with quantitative formula. (If detailed composition formula is not attached with the CPP, a stamped document from the drug authority at country of origin consists of the composition formula should be submitted along with the registration file).

**2. Marketing licensing or authorization in other countries**:

- Provide a list of the countries in which this product has been granted license for marketing,
- Photocopy of marketing authorization in each of these countries

**3. Composition formula from the manufacturer**:

- Provide a list of all components of the dosage form including components of the mixture (e.g. colorants, coating, capsule shell),if any.
- Provide amount per unit basis and per batch formula (including overages, if any with justification).
- Function of components.
- Specification of components.
- Source of components.

**4. Product information:**

- Summary of product characteristics(SPC)
- Product Package insert in Arabic and/or English.

**5. Label of the product (inner and outer pack) including e.g. (diluent, solvent …..etc.) (refer to attached labeling requirement)**

5.1. Artwork of the finished product (Colored mock-ups) with dimensions.

- Artwork for the shape of the outer pack.
- Artwork for the shape of the inner pack.

5.2. Photos:

- Photo of outer pack for all sides.
- Photo of inner pack for all sides.
- Photo of the tablet or capsule by both sides.

**6. Certificate(s) of analysis of drug substance(s)(on a headed paper) from manufacturer and supplier.**

**7. Certificate of analysis – excipients (In-actives) from manufacturer and supplier.**

**8. Description of manufacturing process and process controls:**

- Flow diagram of the manufacturing process.

- Provide a detailed method of manufacturing procedure for the finished product, including packaging and showing all materials used in the manufacturing process even if they do not appear in the final product.
- In process control contain critical steps tests and specifications.

**9. Declaration from the manufacturer of the finished product that the product is free from Alcohol for oral liquid dosage form.**

**10. Certificate stating that the product is free from (TSE) and a halal certificate if the source of the active, inactive and/or any other substance within the product is from animal origin.**

**11. Certificate of analysis of primary packaging materials from supplier.**

**12. Specification(s) of the finished product.**

**13. Certificate of analysis of the finished Product (on original headed paper).**

**14. Stability data of the finished product:**

- Finished product: According to WHO climatic zone 4A covering the proposed shelf life.
- For three commercial batches.
- Recent study (if not recent ongoing stability study along with old one should be attached).

**14.1. Solvent (diluent):**

- In case of solvent (diluent) submit the same requirements of the finished products as in point

**14.2. In-use stability study:**

- A minimum of two batches, at least pilot-scale batches.

**15. Method of analysis and validation of the finished product**

15.1. Method of analysis of the finished product.
15.2. Validation of analytical Procedures(In case of non-pharmacopeia).
15.3. Verification (in case of official Pharmacopeia)
15.4. Comparison study between pharmacopeial method and in-house method with statistical data (in case of submission of in-house method in presence of pharmacopeial method)

**16. Bioequivalence studies (if required).**

NOTE:

- These requirements apply to all human medicinal products except biological products.
- Company should provide CD as CTD format for originator products.

http://www.nmpb.gov.sd/en/drug_hu_forgin.php?num=5

**Requirements for the Registration of innovator and biological Human Medicinal Products**

**A. General Requirements:**

1. The manufacturing plants should be registered with in the NMPB.
2. The pharmaceutical product with the same specification should be registered and freely sold in the country of origin and if not please give justifications (Justification should be attached).

3. The application form should be filled by the applicant.
4. The prescribed fees should be paid.
5. All documents should be in English and/or Arabic.

**B. Specific Requirements:**

1. **Modules 1**: Regional Administrative Information.
2. **Modules 2**: Common Technical Document Summaries.
3. **Modules 3**: QUALITY.
4. **Modules 4**: Non-Clinical Study Reports.
5. **Modules 5**: Clinical Study Reports.

**NOTE: Refer to Annex 1 (CTD check list).**
**Annex (1)**

## Check List Regarding CTD Submission for Drug Registration Purposes

| |
|---|
| **Drug Name :**<br>**Dosage form:**<br>**Concentration:** |
| **Application Type: (check one)**<br>• Innovator drug<br>• Biological drug<br>• Bio similar drug |
| **Submission type : (check one)**<br>• Complete manufacturing<br>• Contract manufacturing<br>• Under License |
| **Pack Size:**<br>**Pack Type:** |
| **Manufacturer:**<br>**Country:**<br>**Marketing Authorization Holder (MAH):**<br>**Country:** |
| **Applicant Name:** |

| Section | Requirements | Company | | |
|---|---|---|---|---|
| | | Yes | No | N.A |
| **Module 1** | **Regional Administrative Information** | | | |
| **1.1** | **Comprehensive Table of content** | | | |
| **1.2** | **Product Information** | | | |
| **1.2.1** | Summary of Product Characteristics (SPC) | | | |
| **1.2.2** | Product Package insert Arabic and/or English. | | | |
| **1.3** | **Label of the product (Inner and outer pack) including e.g. (diluent, solvent …..etc.)** | | | |
| **1.3.1** | **Artwork of the finished product (Colored Mock-ups) with dimensions**. | | | |
| 1.3.1.1 | Artwork for the shape of the outer Pack. | | | |
| 1.3.1.2 | Artwork for the shape of the inner Pack | | | |
| **1. 3.2** | **Photos** | | | |
| 1.3.2.1 | Photo of outer Pack for all sides. | | | |
| 1.3.2.2 | Photo of inner Pack for all sides. | | | |
| 1.3.2.3 | Photo of the tablet or capsule by both sides. | | | |
| **1.4** | **Summary of B.E** | | | |
| **1.5** | **Information on the experts** | | | |
| **1.6** | **Environmental Risk Assessment** | | | |
| **1.7** | **Pharma covigilance** | | | |
| **1.8** | **Certificates** | | | |
| **1.8.1** | **CPP (Certificate of Pharmaceutical Product)(Valid)** | | | |
| 1.8.1.1 | As WHO format | | | |
| 1.8.1.2 | Issued by the Health authority in the exporting country | | | |
| 1.8.1.3 | Authenticated by Sudan Ministry of Foreign Affairs | | | |
| 1.8.1.4 | The composition formula in (CPP) should show the active and inactive ingredients with quantities | | | |
| **1.8.2** | **Certificate(s) of analysis - Drug Substance(s) (on a headed paper and printed) from manufacturer and supplier** | | | |
| **1.8.3** | **Certificate of analysis - Finished Product (on a headed paper and printed)** | | | |
| **1.8.4** | **Certificate of analysis – Excipients from manufacturer and supplier** | | | |
| **1.8.5** | **Declaration from the manufacturer of the finished product that the product is free from Alcohol for oral liquid dosage form.** | | | |
| **1.8.6** | **Certificate stating that the product is free from (TSE) and a halal certificate if the source of the** | | | |

| | | | | |
|---|---|---|---|---|
| | **active, inactive and/or any other substance within the product is from animal origin** | | | |
| **1.9** | **Marketing licensing or authorization in other countries:** | | | |
| **1.9.1** | A list of the countries in which this product has been granted license for marketing, | | | |
| **1.9.2** | Photocopy of marketing authorization in each of these countries. | | | |
| **1.10** | **The diluents and coloring agents in the product formula** | | | |
| **1.11** | **Patent Information** | | | |
| **1.12** | **Letter of access or acknowledgment to DMF** | | | |
| **1.13** | **Responses to questions** | | | |

| **Module 2** | **Common Technical Document Summaries** | | | |
|---|---|---|---|---|
| **2.1** | **Table of Contents of Module 2-5** | | | |
| **2.2** | **Introduction** | | | |
| **2.3** | **Quality Overall Summary** | | | |
| **2.3.S** | **Drug substance** | | | |
| 2.3.S.1 | General Information | | | |
| 2.3.S.2 | Manufacture | | | |
| 2.3.S.3 | Characterization | | | |
| 2.3.S.4 | Control of Drug Substance | | | |
| 2.3.S.5 | Reference Standards or Materials | | | |
| 2.3.S.6 | Container/Closure System | | | |
| 2.3.S.7 | Stability | | | |
| **2.3.P** | **Drug Product** | | | |
| 2.3.P.1 | Description and Composition of the Drug Product | | | |
| 2.3.P.2 | Pharmaceutical Development | | | |
| 2.3.P.3 | Manufacture | | | |
| 2.3.P.4 | Control of Excipients | | | |
| 2.3.P.5 | Control of Drug Product | | | |
| 2.3.P.6 | Reference Standards or Materials | | | |
| 2.3.P.7 | Container/Closure System | | | |
| 2.3.P.8 | Stability | | | |
| **2.3.A** | **Appendices** | | | |
| 2.3.A.1 | Facilities and Equipment | | | |
| 2.3.A.2 | Adventitious Agents Safety Evaluation | | | |
| 2.3.A.3 | Novel Excipients | | | |
| **2.3.R** | **Regional Information** | | | |
| **2.4** | **Non clinical Overview** | | | |
| **2.5** | **Clinical Overview** | | | |
| **2.6** | **Non-Clinical Written and Tabulated Summaries** | | | |
| **2.6.1** | **Introduction** | | | |

| | | | | |
|---|---|---|---|---|
| **2.6.2** | **Pharmacology Written Summary** | | | |
| **2.6.3** | **Pharmacology Tabulated Summary** | | | |
| **2.6.4** | **Pharma cokinetics Written Summary** | | | |
| **2.6.5** | **Pharma cokinetics Tabulated Summary** | | | |
| **2.6.6** | **Toxicology Written Summary** | | | |
| **2.6.7** | **Toxicology Tabulated Summary** | | | |
| **2.7** | **Clinical Summary** | | | |
| **2.7.1** | **Summary of Bio pharmaceutic and Associated Analytical Methods** | | | |
| **2.7.2** | **Summary of Clinical Pharmacology Studies** | | | |
| **2.7.3** | **Summary of Clinical Efficacy** | | | |
| **2.7.4** | **Summary of Clinical Safety** | | | |
| **2.7.5** | **References** | | | |
| **2.7.6** | **Synopses of Individual Studies** | | | |

| **Module 3** | **QUALITY** | | | |
|---|---|---|---|---|
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| **3.2** | **BODY OF DATA** | | | |
| **3.2.S** | **DRUG SUBSTANCE** | | | |
| **3.2.S.1** | **General Information** | | | |
| 3.2.S.1.1 | Nomenclature | | | |
| 3.2.S.1.2 | Structure | | | |
| 3.2.S.1.3 | General Properties | | | |
| **3.2.S.2** | **Manufacture** | | | |
| 3.2.S.2.1 | Manufacturer( s ) | | | |
| 3.2.S.2.2 | Description of Manufacturing Process and Process Controls | | | |
| 3.2.S.2.3 | Control of Materials | | | |
| 3.2.S.2.4 | Control of Critical Steps and Intermediates | | | |
| 3.2.S.2.5 | Process Validation and/or Evaluation | | | |
| 3.2.S.2.6 | Manufacturing Process Development | | | |
| **3.2.S.3** | **Characterization** | | | |
| 3.2.S.3.1 | Elucidation of Structure and Other Characteristics | | | |
| 3.2.S.3.2 | Impurities | | | |
| **3.2.S.4** | **Control of the Drug Substance** | | | |
| 3.2.S.4.1 | Specifications | | | |
| 3.2.S.4.2 | Analytical Procedures(Include but not limited to | | | |
| 3.2.S.4.3 | Validation of Analytical Procedures | | | |
| 3.2.S.4.4 | Batch Analyses (3 batches) | | | |
| 3.2.S.4.5 | Justification of Specification | | | |
| **3.2.S.5** | **Reference Standards or Materials** | | | |
| **3.2.S.6** | **Container/Closure Systems** | | | |

| | | | | |
|---|---|---|---|---|
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| 3.2.S.7.2 | Post-Approval Stability Protocol and Stability Commitments | | | |
| 3.2.S.7.3 | Stability Data | | | |
| **3.2.P** | **DRUG PRODUCT** | | | |
| **3.2.P.1** | **Description and Composition of the Drug Product** | | | |
| **3.2.P.2** | **Pharmaceutical Development** | | | |
| 3.2.P.2.1 | Components of the Drug Product | | | |
| 3.2.P.2.2 | Drug Product | | | |
| 3.2.P.2.3 | Manufacturing Process Development | | | |
| 3.2.P.2.4 | Container Closure System | | | |
| 3.2.P.2.5 | Microbiological Attributes | | | |
| 3.2.P.2.6 | Compatibility | | | |
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| 3.2.P.3.1 | Manufacturer( s ) | | | |
| 3.2.P.3.2 | Batch Formula | | | |
| 3.2.P.3.3 | Description of Manufacturing Process and Process Controls | | | |
| 3.2.P.3.4 | Controls of Critical Steps and Intermediates | | | |
| 3.2.P.3.5 | Process Validation and/or Evaluation | | | |
| **3.2.P.4** | **Control of Excipients** | | | |
| 3.2.P.4.l | Specifications | | | |
| 3.2.P.4.2 | Analytical Procedures, include but not limited to | | | |
| 3.2.P.4.3 | Validation of Analytical Procedures | | | |
| 3.2.P.4.4 | Justification of Specifications | | | |
| 3.2.P.4.5 | Excipients of Human or Animal Origin | | | |
| 3.2.P.4.6 | Novel Excipients | | | |
| **3.2.P.5** | **Control of Drug Product** | | | |
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| 3.2.P.5.2 | Analytical Procedures(Include but not limited to | | | |
| 3.2.P.5.3 | Validation of Analytical Procedures | | | |
| 3.2.P.5.4 | Batch Analyses (3 batches) | | | |
| 3.2.P.5.5 | Characterization of Impurities | | | |
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http://www.nmpb.gov.sd/en/drug_hu_forgin.php?num=6

## Requirements for Variations

**General Notes:**

It is important to note that "National Medicines and Poisons Board NMPB" reserves the right to request any additional information and data not specifically described in this document, in order to assess adequately the safety, efficacy and quality of drug products.

Applicants should be aware that deficient documentation can lead to rejection of the application.

**A. Variation required submission of application:**

Variations that affect the pharmaceutical and non-pharmaceutical products or their manufacturers are classified as follows:

1. Change in the name and /or address of the marketing authorization holder (MAH).
2. Change in the manufacturing Site of the finished product.
3. Changes in the composition formula of the finished Product (excipients).
4. Change in trade name of medicinal product.
5. Change in any part of the secondary/outer pack of the finished product.
6. Change in any part of the primary/inner pack of the finished product.
7. Change in the shelf life of finished product.
8. Change in the finished product specifications.
9. Change/addition in pack size of the finished product.
10. Change in the shape or dimensions of the pharmaceutical form (for solid dosage form)

11.Change of the name / Modification of the address of a foreign manufacturer
12. Changing or adding a new agency.

**B. Variation not required submission of application:**
For any change (s) other than the previously mentioned variation in(A), a notification letter only from the manufacturer to submitted to NMPB.

The following documents should take into consideration when submitting any variation application:
**1. Change in the name and /or address of the marketing authorization holder (MAH):**
1.1 Justification for changing the name and /or address of the marketing authorization holder (MAH).
1.2 A formal document from a relevant official body in which the new name or new address is mention.
1.3 Replacement of the relevant pages of the Dossier that affected by the variation (inner, outer pack).

**2. Change in the manufacturing Site of the finished product:**
2.1 Justification for changing the manufacturing site.

2.2 Replacement of the relevant pages of the dossier that are affected by the variation (Inner, outer pack).

2.3 Certificate of a Pharmaceutical Product (CPP) (for foreign products) from the relevant competent health authority for human & veterinary Pharmaceutical Products (The composition should be attached with CPP), and free sale certificate for cosmetic, dietary supplement& health products, and European Certificate (EC) or FDA for medical devices.

2.4 Real time stability studies from the new manufacturing site for at least two pilot-scale batches and commitment letter to complete the stability studies to cover the shelf life must be submitted **(must cover at least three months).**

2.5 A declaration by the company that the manufacturing process will remain the same. In addition, the API(s), excipient(s) and their source(s), dosage form, concentration, the primary and secondary packaging, labeling, and all specifications for the product must remain the same as previously approved in the old site. A clarification of any proposed change(s) to the manufacturing of the product at the new manufacturing site should be provided and justified.

2.6 For solid dosage forms, data from comparative dissolution tests with demonstration of similarity of dissolution profile, performed on the last three batches from the previous site and the first three batches from the new site should be submitted.

2.7 Validation of the analytical methods needed for batch release (according to the release specifications) from the proposed secondary packaging site and/or validation for transportation process from manufacturing site to secondary packaging site along with release certificate from secondary packaging site covering all processes from receiving the semi-finished product to final pack.

If the change is related to Manufacturer responsible for quality control or the finished product release the stability study is not required.

**3. Changes in the composition formula of the finished Product (excipients):**

3.1 Justification for the change/choice of excipients etc. must be given by appropriate development pharmaceutics.

3.2 Copy of the approval document (for the change)from health authority in country of origin.

3.3Certificate of a Pharmaceutical Product (CPP)(for foreign products) from the relevant competent health authority for human& veterinary Pharmaceutical Products (The composition should be attached with CPP) and free sale certificate for cosmetic, dietary supplement &health products.

3.4 Real time stability studies from the new manufacturing site for at least two pilot-scale batches and commitment letter to complete the stability studies to cover the shelf life must be submitted **( must cover at least three months)**.

3.5 A certificate stating that the product is free from (TSE/BSE) and a Halal certificate if source of the active, Inactive and/or any other substance within the Product is of animal source.

3.6 Comparative table that clearly outline the change (current and proposed).

3.7 For solid dosage forms, comparative dissolution Profile data of at least two pilot scale batches of the finished product in the new and old composition. For herbal medicinal products, comparative disintegration data may be acceptable. (Unless the change is related to the coloring of flavoring agent)

3.8For veterinary medicines intended for use in food producing, justification that the excipient does not have pharmacological activity at the dose at which it is administered to the target animal.

**4. Change in trade name of medicinal product:**

4.1 Justification for changing the trade name of medicinal product.

4.2 Replacement of the relevant pages of the dossier that are affected by the variation (Inner, outer pack).

4.3 Certificate of a Pharmaceutical Product (CPP)(for foreign products) from the relevant competent health authority for human& veterinary Pharmaceutical Products (The composition should be attached with CPP), and free sale certificate for cosmetic, dietary supplement &health products, and European Certificate (EC) or FDA for medical devices.

**5.Change in any part of the secondary/outer pack of the finished product:**

5.1New outer pack artwork (Colored Mock- up)

**6. Change in any part of the primary/inner pack of the finished product:**

6.1 New inner pack artwork (Colored Mock- up).

6.2 Real time stability studies from the new manufacturing site for at least two pilot-scale batches and commitment letter to complete the stability studies to cover the shelf life must be submitted (must cover at least three months).

**7. Change in the shelf life of finished product:**

**A. Reduction of shelf life of finished:**
1. Justification for the reduction in the shelf-life from the manufacturer.
2. Copy of the approval document (for the change) from health authority in country of origin.

**B. Extension of shelf life of finished:**
1. Copy of the approval document (for the change) from health authority in country of origin.
2. Recent real time stability studies covering the proposed shelf life, on at least three production scale batches of the finished product and/or after first opening or reconstitution (in-use stability).

**8. Change in the finished product specifications:**

8.1 Justification of the new specification parameter and limits.
8.2 Comparative table of current and proposed specifications.
8.3 Details of any new analytical method and validation data.
8.4 Comparative study between pharmacopeia method and in-house method with statistical data (in case of in-house method)

**9. Change/ addition in pack size of the finished product:**

9.1 Justification for the new/remaining pack-size, showing that the new/remaining size is/are consistent with the dosage regimen and duration of use as approved in the summary of product characteristics.
9.2 Real time stability studies for at least two pilot-scale batches and commitment letter to complete the stability studies to cover the shelf life must be submitted **(must cover at least three months).**
9.3 A declaration that material of the primary/ inner package has not been changed from the previously approved one.

**10. Change in the shape or dimensions of the pharmaceutical form (for solid dosage form):**

Copy of the approval document (for the change) from health authority in country of origin.

Comparative dissolution data on at least one pilot batch of the current and proposed dimensions. For herbal product comparative disintegration data may be acceptable.
Photo of new Solid dosage form of both the sides is needed.

**11. Change of the name / Modification of the address of a foreign manufacturer:**

11.1 A valid copy of the manufacturing license from the regulatory authority in the country of origin in which the new name or modified address of the manufacture mentioned.

11.2 Valid c GMP certificate from the competent authority in the country of origin in which the new name or modified address is mentioned or ISO for medical devices.

11.3 A declaration from the regulatory authority in the country of origin that the manufacturer has renamed or modified its address only without any change in the manufacturing site. EC or FDA for medical devices.

**12. Changing or adding a new agency:**

A valid agency agreement with the manufacturer authenticated by the Registrar of Companies from the Ministry of Justice is needed.

List of products in case of partial agency stamped by the Registrar of Companies from the Ministry of Justice is needed.

The termination letter from the manufacturer of the previous agency if any is required.

## REFERENCES:


- Drug registration requirements in Sudan
http://pharmabiz.com/Services/ExportImport/Countries/Sudan.aspx


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**Details of Indian Embassy abroad:** http://www.eoikhartoum.gov.in/index.php

**Details of importing country Embassy in India:** http://www.sudanembassyindia.org/