RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES GOVERNING THE USE AND DISTRIBUTION OF ETHYL ALCOHOL IN RWANDA

MARCH 2026

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA), established by Law Nº 003/2018 of 09/02/2018, is mandated to protect public health, and as stipulated in Article 3 (13), Rwanda FDA regulates ethyl alcohol which serves as both a vital industrial commodity and a potential health hazard if mismanaged. By doing so, Rwanda FDA ensures that the ethyl alcohol circulating on the Rwandan market meets the highest standards of quality and safety.

The achievement of a secure market depends on the synergy between regulatory oversight and the proactive adherence to the Law by all stakeholders. In accordance with Law Nº 47/2012 of 14/01/2013, particularly Article 3, Rwanda FDA has institutionalized strict requirements for the importation, registration and licensing of premises dealing with ethyl alcohol. This legal framework ensures that from the point of entry to the point of consumption, the integrity of the product remains uncompromised.

These guidelines provide a clear pathway for dealers involved in manufacturing, storage, packaging, distribution, and use. By detailing application requirements for importation, registration and licensing, Rwanda FDA aims to eliminate technical and administrative bottlenecks and minimize queries, thereby accelerating service delivery. Beyond licensing, these guidelines encompass the critical requirements of product registration, ensuring chemical purity before market entry, and robust import and export controls to maintain a secure trade channel.

Furthermore, the guidelines establish a framework for safety monitoring and risk-based inspections. This ongoing surveillance allows for the real-time identification of health hazards, ensuring that non-compliant products are swiftly removed from the market. All dealers must prioritize consumer health benefits by maintaining secure technologies, processes and adequate premises. By aligning operations with these requirements, stakeholders contribute to a safer country where ethyl alcohol is consistently safe and professionally managed.

Prof. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

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ADOPTION OF STAKEHOLDERS' COMMENTS	
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Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
	0	First Issue

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ACRONYMS AND ABBREVIATIONS

CAPA	Corrective Actions and/or Preventive Actions
GMP	Good Manufacturing Practices
IRIMS	Integrated Regulatory Information Management System
ISO	International Organization for Standardization
QA	Quality Assurance
QC	Quality Control
RDB	Rwanda Development Board
SOP	Standard Operating Procedures

GLOSSARY / DEFINITIONS

In these guidelines, unless the context otherwise requires:

"**Alcohol advertisement"** means information published in any form and through any means, by which it is sought to influence consumers' choices, in connection with the acquisition and consumption of alcohol products, use, and the commercial, economic, and financial activities of enterprises.

"**Alcohol control"** includes the totality of means employed in this guidelines and other applicable Laws, including the production of alcohol products, their import, domestic trade, consumption, and advertisement.

"**Alcohol products"** means non denatured ethyl alcohol, denatured ethyl alcohol (including dehydrated and denatured ethyl alcohol (ethanol), ethyl alcohol for technical purposes, alcoholic beverages, ingredients and raw materials that contain ethyl alcohol.

"**Applicant**" means a person, company or their representative manufacturing or selling ethyl alcohol applying for inspection for suitability of premises licensing and registration of the product.

"**Authorization**" means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; it includes premise registration certificate and licenses.

"Authorized person'' means an individual recognized by the authority as having the necessary basic scientific and technical background and experience.

"**Business Operator**" means a person, or company who undertakes, whether for profit or not, any activities related to manufacturing, distribution, storing, exhibit, wholesale or retail activities of regulated products including ethyl alcohol .

"**Consignment**" means a quantity of goods that are sent to a consignee or a place covered by a single transport documents on a single customs' document.

"**Container**" means the material employed in the packaging of ethyl alcohol and other raw materials. Containers include primary, secondary, and tertiary containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary packaging encloses the primary packaging and tertiary packaging material means an outer carton in which multiples of saleable units are packed. Secondary and tertiary containers are not intended to be in direct contact with the product.

"**Corrective action and preventative actions (CAPA**) means a system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.

"Critical Deficiency" when the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to personnel or environment is highly probable, including life threatening situation.

"Critical equipment": means any piece of the equipment, instrumentation, or systems, whose malfunction or failure may cause variation in the quality and safety of the products.

"**Denatured Ethyl alcohol**" Ethyl Alcohol to which allowable denaturant(s) have been added in order to render it unsuitable for human consumption.

"**Distribution** "The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products.

"Ethyl alcohol" also called ethanol or ethylic alcohol (CH_3CH_2OH) is a colourless, volatile, and flammable organic liquid, and it is obtained through fermentation or chemical synthesis. As polar organic compound ethyl alcohol is highly soluble in water, and it is broadly used in alcoholic beverages and other food products, antiseptics and disinfectants, as solvent in paints/varnishes, cosmetics, and in various laboratory activities.

"Evade" means the act of avoiding interaction with an inspector to prevent or delay an inspection to take place, including but not limited to providing repetitive excuses for why an inspection cannot take place at a particular time, closing the entire facility temporarily, not responding to calls or notifications, or misleading the inspector about the location of operations.

"**Good Distribution Practice (GDP)**" is a part of quality assurance that ensures that the quality of a product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from unapproved, substandard, falsified or misbranded products.

"**Good Manufacturing Practices (GMP)**" means that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation, Clinical Trial Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control.

"**Good Storage Practices (GSP)**" is that part of quality assurance that ensures that the quality of a product is maintained by means of adequate control throughout the storage thereof.

"Inspector" means a person appointed, authorized and designated by the Rwanda FDA in accordance with laws tasked with performing inspection-related duties.

"Labeling" means process of identifying a product including the following information, as appropriate: name of the product, active ingredient(s), type and amount, batch number, expiry date, special storage conditions or handling precautions, directions for use, warnings and precautions, names and addresses of the manufacturer and/or the supplier.

"Major Deficiency" means a deficiency that is not a "Critical" deficiency, but could have major effects on the overall safety, efficacy and quality of the products. This consists of several "Minor/Other" related deficiencies, none of which on its own may be "Major", but which may together represent a "Major" deficiency or systems failure and should be explained and reported as such.

"Manufacturer" means a person or corporation, or other entity engaged in the business of manufacturing regulated products including ethyl alcohol-based products.

"Minor/Other Deficiency" means a deficiency that is not classified as either "Critical" or "Major", but indicates failure to meet the standards of premises suitability. A deficiency may be judged as "Minor" because there is insufficient information to classify it as "Critical" or "Major".

"Obstruction" means the deliberate act of hindering, interfering with, or preventing an ongoing inspection including but not limited to refusing access to certain areas of the premises, hiding evidences, or providing forged records, threatening the inspector, or tampering with samples they require for analysis.

"Premises" means any plot of land, buildings or boats, aircraft, vehicles, a part of a building, a place of storage, manufacturers, distributors, wholesalers, retailers of ethyl alcohol whether open or closed.

"**Qualified personnel**": means an individual who by possession of a recognized degree, who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter.

"**Retailer**" means a person or body corporate permitted and authorized to store and sell under the laws and regulations in Rwanda pertaining to ethyl alcohol to the public in relatively small quantities for use rather than for resale.

"**Storage**" The storing of products up to their point of use.

"Substandard ethyl alcohol" means ethyl alcohol that do not comply with established provisions of ethyl alcohol legislation such as Laws, Regulations, Guidelines, Standards, Instructions, misrepresented through false, misleading or inaccurate labelling, certification or declarations, or failing to comply with applicable quality, safety or specification standards established by the Authority.

"Substantial modification" means a change to the premises, equipment, personnel, procedures, and processes that is likely to have a significant impact and affect the quality, safety and the integrity of the products manufactured, stored, distributed, and used.

"Suspension of a license" means a temporary cessation of the license issued to the manufacturer, storage facility, distributor, wholesaler, or retailer of regulated products including ethyl alcohol due to violation of conditions of issue.

"**Wholesaler**" is an entity that is authorized to carry on the business of selling regulated products including ethyl alcohol in large quantities to other authorized sellers with the exception of dispensing or providing the product(s) directly to the consumer.

"Withdrawal of a license" means termination of a license issued to the manufacturer, storage facility, distributor, wholesaler, or retailer of regulated products including ethyl alcohol due to violation of conditions of issue.

"Traceability" means the ability to track the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of a given product.

"Transit" means the period during which products are in the process of being carried, conveyed, or transported, over or through a passage or route to reach the destination.

"**Transporter**" means a person who transports products from one point to another within the supply chain.

"Unapproved ethyl alcohol" means ethyl alcohol that has not been duly authorized for use by the Authority in accordance with applicable laws and regulatory requirements, including ethyl alcohol that is manufactured, imported, stored, distributed, marketed, supplied, sold or otherwise handled without a valid corresponding license issued by the Authority.

In these Guidelines, the following verbal forms are used:

"**shall**" indicates a requirement;
"**should**" indicates a recommendation;
"**may**" indicates permission; and
"**can**" indicates a possibility or a capability.

CHAPTER 1: INTRODUCTION

1.1 Purpose

The purpose of these guidelines is to establish a comprehensive national regulatory framework for the manufacture, importation/exportation, storage, distribution, and use of ethyl alcohol, with the primary objective of safeguarding public health. These provisions are intended to prevent diversion for illicit consumption or misuse, while ensuring that authorized industries, pharmaceutical sector, food sector, public health laboratories, and cosmetic manufacturers have reliable access to the appropriate grades of ethyl alcohol required for their legitimate operations.

1.2 Scope

These guidelines apply to all entities engaged in the supply chain of ethyl alcohol, including manufacturers, importers/exporters, distributors, and end-users in the medical, public health laboratory, cosmetics, pharmaceutical and food sectors. The provisions encompass all grades of both denatured and undenatured ethyl alcohol intended for medical use, pharmaceutical and food processing, preservation, flavoring, and other authorized applications.

These guidelines do not apply to all ethyl alcohol-based products consumed as final products.

1.3 Submission of applications

An application for ethyl alcohol registration and import/export, premises registration and licensing shall be made in writing via a cover letter and application form dated and signed by the applicant. The submitted cover letter and application form should be accompanied by the required documents as described in these guidelines.

All the applications shall be submitted to Rwanda FDA *via* Integrated Regulatory Information Management System (IRIMS) platform: https://www.irims.rwandafda.gov.rw

1.4 Application processing timelines and corresponding approval validity

The application processing timelines and corresponding approval validity are as follow:

a. Import/export license is processed within 3 working days and its validity is 6 months,

b. Premises registration and licensing process takes 30 working days. The Premises registration certificate validity is issued once for all and the manufacturing license is valid for 3 years, while the premises license is valid for 5 years,

c. Good Manufacturing Practice processing time is 150 days and its validity is 3 years,

d. The registration processing timeline is 90 working days and the registration certificate validity is 5 years.

CHAPTER 2: LICENSING OF MANUFACTURERS, DISTRIBUTORS, WHOLESALERS AND RETAILERS OF ETHYL ALCOHOL

2.1 Inspections

Rwanda FDA shall conduct an inspection to confirm the compliance requirements in order to grant or re-grant a manufacturing or premises license or an approval of a substantial modification, and to ensure that the facilities are suitable to accommodate intended activities.

Premises that do not comply with the requirements for suitability shall not be approved.

2.2 Types of inspections

The following types of inspection may be conducted:

a) **The routine inspection:** is a full inspection of all applicable components of licensing requirements. It may be conducted when the facility is :

i. Newly established,
ii. Requests for renewal of a manufacturing or premises license,
iii. Has a history on non-compliance with legal provisions (Laws and regulations),
iv. Has introduced new production line(s) or new product(s), or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, etc.,
v. Has made any substantial modification to registered and licensed premise information.

b) **Follow-up inspections** (re-inspections) are conducted to monitor the effectiveness result of corrective measures. They are normally carried out depending on the nature of the defects and the work to be undertaken. They are limited to specific licensing requirements that have not been observed or that have been inadequately implemented.

c) **Special inspections** may be necessary to conduct spot checks following complaints, product recalls related to suspected quality defects in products or reports of adverse reactions to the product. Such inspections may focus on a single product, a group of related products, or on specific operations such as mixing, labelling or packaging.

2.3 Categorization of inspection compliance

The following section provides a classification of compliance based on risk factors to guide Rwanda FDA in decision-making following a premises inspection.

The regulatory actions shall be classified as in the following non-compliance categories:

a) Critical
b) Major
c) Minor

2.3.1 MANUFACTURING FACILITIES

2.3.1.1 Critical non-compliances

a) Premises

i. Site location which does not comply with the environmental requirement to manufacture ethyl alcohol,
ii. No air filtration system to eliminate airborne contaminants that are likely to be generated during manufacture or packaging,
iii. Generalized malfunctioning of the ventilation system(s) with evidence of widespread cross-contamination,
iv. Inadequate segregation of manufacturing process and testing areas from other manufacturing areas that may pose serious health hazards and cross contamination of products,
v. Lack of clean water, and waste water treatment system,
vi. Surface finish: Production floor area, ceiling and walls that are not seamless and easy to clean.

b) Equipment

i. Equipment used for manufacturing operations of ethyl alcohol not qualified with evidence of malfunctioning,
ii. Evidence of contamination of ethyl alcohol by foreign materials such as grease, oil, rust particles from the equipment.

c) Personnel

Staff in charge of quality control or production do not hold suitable academic degrees in a science related to the supervised work, and insufficient practical experience in their area of responsibilities.

d) Sanitation

i. Evidence of widespread accumulation of residues/extraneous matter indicative of inadequate cleaning,
ii. Evidence of gross infestation.

2.3.1.2 Major non-compliances

a) Premises

i. Malfunctioning of the ventilation system that could result in possible localized or occasional cross-contamination,

ii. Accessory supplies (steam, air, nitrogen, dust collection etc.) not qualified,
iii. Heating Ventilation Air Conditioning (HVAC) not qualified,
iv. Temperature and humidity not controlled or monitored when necessary,
v. Damages to walls/ceilings immediately adjacent or above manufacturing areas or equipment where the product is exposed,
vi. Un-cleanable surfaces created by pipes, fixtures or ducts directly above ethyl alcohol or manufacturing equipment,
vii. Surface finish (floors, walls, ceilings) that do not permit effective cleaning,
viii. Insufficient manufacturing space that could lead to mix-ups,
ix. Quarantine areas accessible to unauthorized personnel and not well marked.

b) Equipment

i. Equipment does not operate within its specifications,
ii. No covers for tanks, hoppers or similar acceptable manufacturing equipment,
iii. Equipment used for manufacturing operation not qualified,
iv. Stored equipment not protected from contaminations,
v. Inappropriate equipment for production: porous surfaces and non-cleanable/material to shed particles,
vi. Equipment location does not prevent cross-contamination or possible mix-ups for operations performed in the common areas,
vii. No calibration program for measuring equipment /no calibration records maintained,
viii. No fire-fighting equipment/Fire alarm systems, emergency doors.

c) Personnel

i. Delegation of responsibilities of key personnel for Quality Control and production to unqualified persons,
ii. Insufficient personnel in Quality Control and Production resulting in high risk to errors.

d) Sanitation

i. Lack of written sanitation program, but premises in acceptable state of cleanliness,
ii. Absence of medical emergency kits,
iii. Absence of Emergency shower.

2.3.1.3 Minor (other) non-compliances

a) Premises

i. Un-trapped floor drains,
ii. Damages to surfaces not directly adjacent or above exposed ethyl alcohol,
iii. Inadequate rest, change, wash-up and toilet facilities.

b) Equipment

i. Insufficient space between equipment and walls to permit cleaning,
ii. Base of immovable equipment not adequately sealed at points of contact,
iii. Defective or unused equipment used for non-critical products not qualified.

c) Sanitation

i. Incomplete written sanitation program,
ii. Sanitation or health and hygiene programs not properly implemented or followed by employees.

2.3.2 DISTRIBUTOR, WHOLESALER OR RETAILER OF ETHYL ALCOHOL

2.3.2.1 Critical Non-Compliances

a) Premises

i. Minimum floor space and height requirements,
ii. Natural/Mechanical ventilation/Air handling unit /Heat, Ventilation and Air Conditioning (HVAC),
iii. Inadequate temperature and humidity monitoring systems,
iv. Surrounding area that can cause contamination from the external environment or other activities,
v. Inadequate floor, ceiling and walls maintenance.

b) Equipment/documentation

i. Lack of secure and lockable storage place for ethyl alcohol and related documentation,
ii. Lack of suitable equipment to properly store ethyl alcohol and related documentation.

c) Personnel

Operating without qualified and authorized persons

2.3.2.2 Major Non-Compliances

a) Premises

i. Damage of walls, ceilings, roof, doors and windows;
ii. Surface finish (floors, walls, ceilings) that do not permit effective cleaning,
iii. Inappropriate Natural/Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC),
iv. Inappropriate temperature and humidity monitoring systems.

b) Equipment/documentation

i. Lack of fire-fighting equipment,
ii. Inappropriate storage furniture (Solid shelves, Pallets),

iii. Inappropriate secure and lockable storage place for ethyl alcohol,
iv. Inappropriate equipment to store the temperature sensitive ethyl alcohol,
v. Lack of premises license documents (import & export documents, distribution records, records of expired/damaged ethyl alcohol),
vi. Lack of appropriate transportation means from the wholesaler store to the retailers,
vii. Inappropriate sanitation facilities (toilets, etc.).

2.3.2.3 Minor (Other) Non-Compliances

i. Lack of appropriate lighting systems,
ii. Premises registration certificate and premises license issued by Rwanda FDA not displayed,
iii. License to practice profession issued by professional bodies of the responsible technician not displayed where applicable,
iv. Temperature monitoring records not updated,
v. Absence of filing systems of documents.

2.4 Requirements to operate as a manufacturer of ethyl alcohol for Pharmaceutical Use

Any person or entity intending to manufacture ethyl alcohol for pharmaceutical use in Rwanda shall obtain a valid manufacturing licence issued by Rwanda Food and Drugs Authority. The manufacturing facility shall comply with Good Manufacturing Practice (GMP) requirements to ensure that ethyl alcohol is consistently produced and controlled according to appropriate quality standards suitable for pharmaceutical use.

Prior to the issuance of the licence, and during routine regulatory oversight, the manufacturing facility shall be subject to GMP inspections conducted by Rwanda FDA. The purpose of these inspections is to verify compliance with national regulatory requirements and internationally recognized GMP standards applicable to the manufacture of pharmaceutical products, active pharmaceutical ingredients (APIs), and pharmaceutical excipients.

GMP inspections shall be conducted in accordance with the Rwanda FDA GMP Guidelines and relevant World Health Organization (WHO) GMP guidelines, including but not limited to the following:

- **WHO TRS 986 Annex 2** – which provides the general principles of Good Manufacturing Practices applicable to the manufacture of pharmaceutical products.

- **WHO TRS 957 Annex 2** – which outlines GMP requirements applicable to the manufacture of active pharmaceutical ingredients.

- **WHO TRS 1060 Annex 3** – which provides guidance on GMP requirements for the manufacture of pharmaceutical excipients.

Other internationally recognized GMP guidelines relevant to the manufacture of pharmaceutical ingredients and excipients may also be applied, including but not limited to:

- **ICH Q7** – which provides internationally harmonized GMP requirements for the manufacture of active pharmaceutical ingredients.

- **IPEC-PQG GMP Guide** – which provides guidance on GMP requirements for the manufacture and supply of pharmaceutical excipients.

Manufacturers shall also ensure that the quality of ethyl alcohol intended for pharmaceutical use complies with applicable pharmacopoeia standards such as **United States Pharmacopeia**, **European Pharmacopoeia**, and **British Pharmacopoeia**.

2.4.1 Documents required for a manufacturer's new application

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premises licensing of ethyl alcohol,
c) Certificate of domestic company registration issued by Rwanda Development Board or equivalent,
d) Architectural plan of the site,
e) Product process flowchart (s),
f) Environment impact assessment report,
g) Proof of payment of the prescribed fees,
h) List of products other than ethyl alcohol to be manufactured,
i) Lease/rent contract of the premises/house,
j) Notarized copy of Degree (and equivalence if applicable) of Responsible Technician,
k) Notarized Valid License of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable,
l) Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance,
m) Valid Contract between the Managing Director of the manufacturing plant and the responsible technician in case the Managing Director is not the responsible technician,
n) Copy of the identity card or passport of both the Managing Director and the responsible technician,
o) Written commitment of the technician, to respect the laws and regulations relating to the manufacturing practices performed and oversight the quality of ethyl alcohol being manufactured,
p) Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable;
q) Curriculum vitae of the responsible technician.

2.5 Requirements to operate a Distributor, wholesaler, or retailer of ethyl alcohol

2.5.1 Premises

a) Location

The premises shall be located in a place where they cannot be contaminated from the external environment or other activities.
The external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

b) Standards of construction

Premises shall be in good state of repair, maintenance and sanitation and shall:

i. Be of a permanent nature,
ii. Being meant for commercial purposes or warehousing,
iii. Be protected against adverse weather conditions including dust, ground water seepage, vermin and pest infestation,
iv. Have adequate space for the carrying out and supervision of the necessary operations,
v. Have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning; and,
vi. Be well lit, ventilated and have appropriate air-control facilities including temperature and humidity,
vii. The process of maintenance and repair shall not, while being carried out, cause any contamination of ingredients or ethyl alcohol,
viii. The premises shall have a regular and sufficient supply of water of suitable quality,
ix. The premises shall have appropriate toilet facilities and appropriate hand washing facilities,
x. The premises shall have sufficient fire-fighting equipment which shall, at all times, be in good condition and accessible.

c) Storage areas

The storage areas for products shall be well covered and off the floor in an area:

i. That is secure and has adequate space,
ii. That is laid out to allow clear separation of different materials and ethyl alcohol to minimize the risk of mix-up;
iii. Access to the materials and goods is restricted to authorized personnel only;
iv. Ethyl alcohol that is temperature sensitive shall be stored adequately,
v. With separate area in the storage facility where recalled, expired or rejected ethyl alcohol shall be stored under lock and key.

d) Minimum floor space and height

i. For a distributor dealing with ethyl alcohol, the total floor space shall have a minimum space of 180 square meters. The sales area shall have a minimum floor space of 30 square meters, and records shall be maintained in this area. The storage areas shall have minimum floor area of 150 square meters; and minimum height of 2.5 meters from the floor to the ceiling.
ii. For a wholesaler dealing with ethyl alcohol, the total floor space shall have a minimum space of 90 square meters. The sales area shall have a minimum floor space of 30 square meters, and

records shall be maintained in this area. The storage areas shall have minimum floor area of 60 square meters; and minimum height of 2.5 meters from the floor to the ceiling.

iii. For a retailer dealing with ethyl alcohol, the sales and administrative area shall have minimum floor space of 30 square meters as whole. The minimum height shall be 2.5 meters from the floor to the ceiling.

2.5.2 Documentation and related controls

All records (including but not limited to invoices, purchase orders, import authorizations, sales and distribution records in the wholesale, importer and retailer's premises).

A copy of premises registration certificate and premises license issued by Rwanda FDA and license to practice profession (where applicable) for the responsible qualified personnel shall be conspicuously displayed in the premises.

2.5.3 Personnel

The authorized person shall have the following minimum qualification:

For a distributor, wholesaler of ethyl alcohol: A bachelor's degree in pharmacy, chemistry or any other relevant qualification.

For a retailer of ethyl alcohol: A2 Level in combination containing chemistry, or biology or any other relevant qualification.

2.5.4 Requirements for new application of distributor, wholesaler or retailer of ethyl alcohol for pharmaceutical use

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premise licensing of ethyl alcohol,
c) RDB registration certificate of the domestic company or equivalent,
d) Lease/rent contract of the premise/house,
e) Evidence of payment of prescribed fees to Rwanda FDA Accounts,
f) Notarized copy of Degree (and Equivalence if applicable) of the authorized person,
g) Notarized valid license to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable,
h) Contract between the managing director and the authorized person in case the Managing Director is not the authorized person,
i) Copy of the identity card or passport of both the managing director and the authorized person,
j) Written commitment of the technician to respect the laws and regulations relating to the management of ethyl alcohol,
k) Signed resignation letter/proof of service delivered issued by the last employer of the authorized person, if applicable;
l) A Detailed curriculum vitae of the authorized person.

2.6 Approval of the premises

Upon approval of findings of the inspection to manufacture, distribute, wholesale, retail of ethyl alcohol; Rwanda FDA shall notify the applicant the decision based on the findings of the inspections. In case of compliance with the premises licensing requirements, GMP certificate and manufacturing license for manufacturer or the premises registration certificate and premises license for distributor, wholesaler and retailer shall be granted to the applicant.

In case of non-compliances with the premises licensing requirements, a feedback letter requesting corrective actions may be issued to the applicant.

2.7. License renewal and substantial modification

The applicant shall inform **Rwanda FDA** any modification carried out for the purpose of its approval.

The Authority may conduct an inspection for confirmation of the compliance requirements in order to re-grant a license or approval of a substantial modification.

2.7.1 Documents required for license renewal

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premise licensing of ethyl alcohol,
c) Notarized degree (or equivalence if applicable) of the authorized person,
d) Recent manufacturing or premises license of the establishment issued by Rwanda FDA,
e) Written commitment of the authorized person, to respect relevant laws and regulations and oversight the quality of products being handled where applicable,
f) Certificate of the domestic company registration,
g) Evidence of payment of prescribed fees,
h) Notarized valid license to practice profession of the authorized person where applicable,
i) Contract between the establishment and the authorized person in charge where the managing director is not the authorized person,
j) Copy of the identity card or passport of both the managing director and the authorized person,
k) The application shall be submitted 2 months before the expiration of the previous license.

2.7.2 Documents required for relocation or additional storage space of the licensed premises

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premises licensing of ethyl alcohol,
c) Original manufacturing or premises license of the establishment issued by Rwanda FDA,
d) New certificate of domestic company registration,
e) Evidence of payment of prescribed fees,
f) Lease contract for the establishment.

2.7.3 Documents required for the change of the authorized person of the licensed premises

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premise licensing of ethyl alcohol,
c) Original manufacturing or premises license of the establishment issued by Rwanda FDA,
d) Certificate of the domestic company registration,
e) Evidence of payment of prescribed fees,
f) Notarized degree (or equivalence if applicable) of the authorized person,
g) Notarized valid license to practice profession of the authorized person where applicable,
h) Contract between the establishment and the authorized person in charge where the managing director is not the authorized person,
i) Written commitment of the authorized person to respect relevant laws and regulations and oversight the quality of products being handled,
j) Copy of the identity card or passport of both the managing Director and the authorized person,
k) Signed resignation letter/proof of service delivered of the outgoing authorized person,
l) Signed resignation letter/proof of service delivered issued by the last employer of the incoming authorized person , if applicable;
m) A detailed curriculum vitae of the authorized person.

2.7.4. Documents required to change the ownership of the licensed premises

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premises licensing of ethyl alcohol,
c) Original manufacturing or premises license of the establishment issued by Rwanda FDA,
d) Notarized sales agreement between former and new owner,
e) New and/or updated certificate of the domestic company registration,
f) Notarized degree (or equivalence degree) of the authorized person where applicable,
g) Notarized valid license to practice profession of the authorized person where applicable,
h) Contract between the establishment and the authorized person in charge where the managing director is not the authorized person,
i) Copy of the identity card or passport of both the new managing director and the authorized person.

2.7.5. Documents required to change the name of the license premises

a) Application letter addressed to the Director General of Rwanda FDA,
b) Duly filled application form: Application form for premises licensing of ethyl alcohol,
c) Original manufacturing or premises license of the licensed premises issued by Rwanda FDA,
d) New certificate of domestic company registration.

2.7.6 Documents required to close the licensed premises

a) Application letter addressed to the Director General of Rwanda FDA,
b) Dully completed application form: Application form for premises licensing of ethyl alcohol,
c) Original of the premises registration certificate issued by Rwanda FDA,
d) Recent license issued by Rwanda FDA,
e) A list of closing stock of products and its intended use.

2.8. GOOD PRACTICES

2.8.1 Good Distribution Practices

Areas, where ethyl alcohol is distributed shall be regularly inspected to ensure that the premises and ethyl alcohol are in an acceptable conditions. The conduct of regular inspections is a responsibility of both the responsible persons and the regulator.

Vehicles used to transport products should be properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates.

The use of vehicles with defects that could affect the quality of ethyl alcohol is not allowed.

2.8.2. Good Storage Practices

Ethyl alcohol shall be stored/displayed separately and away from all other materials to avoid any possibility of a source of fire, contamination and confusion with other materials.

Areas, where ethyl alcohol is stored, shall be regularly inspected to ensure that the premises and ethyl alcohol are in an acceptable conditions.

2.8.3. Good Manufacturing Practices

Ethyl alcohol manufacturers shall have systems, facilities and operations that comply with guidelines on good manufacturing practices as adopted by Rwanda FDA.

Areas, where ethyl alcohol is manufactured shall be regularly inspected to ensure that the premises and ethyl alcohol are in an acceptable conditions.

For the GMP Certificate renewal purpose, the application shall be submitted 6 months before the expiration of the previous certificate.

2.8.4. Installation of Remote Monitoring Systems

A qualified person shall install and maintain an appropriate electronic surveillance system, including closed-circuit television (CCTV) or equivalent digital monitoring technologies, to enable real-time and recorded remote viewing of operations within the premises.

The remote viewing system shall:

- Cover all critical operational areas, including:
    - Storage areas for ethyl alcohol
    - Receiving and dispatch zones
    - Processing or repackaging areas (where applicable)

  - Entry and exit points
- Be designed to ensure continuous monitoring of activities that may pose regulatory or diversion risks, in line with risk-based control approaches.
- Operate 24 hours a day, with minimal downtime and appropriate backup systems.
- Retain recorded data for a minimum period of thirty days in the monitoring system
- Retain historical data for a minimum period of one year in other suitable data storage devices

2.8.4.1. Technical and Operational Requirements

The remote viewing system shall:

- Provide clear, high-resolution images sufficient for regulatory inspection and evidence.
- Include date and time stamping on all recordings.
- Be protected against tampering, unauthorized access, or data loss, including the use of secure servers and access controls.

2.8.4.2. Access to the Rwanda FDA

For the purposes of these regulations, the licensed person shall:

- Grant Rwanda FDA unrestricted, real-time remote access to the monitoring system at all times.
- Provide the Rwanda FDA with:
  - Secure login credentials or dedicated access channels
  - Technical support necessary to facilitate access
- Ensure that such access allows the Rwanda FDA to:
  - Monitor operations remotely
  - Review historical recordings
  - Extract or download footage for regulatory purposes

2.8.4.3. Compliance and Maintenance

The licensed person shall:

- Ensure the system is regularly maintained, calibrated, and functional at all times.
- Immediately notify the Rwanda FDA of:
  - Any system failure or interruption
  - Any compromise in data integrity or access
- Restore functionality within a timeframe specified by the Rwanda FDA.

Failure to maintain a functional system shall constitute a regulatory non-compliance.

2.8.4.4. Data Integrity and Confidentiality

- All recorded data shall be considered as critical records and must be:
  - Accurate, complete, and unaltered
  - Readily retrievable upon request

- The licensed person shall ensure confidential handling of data, while not restricting regulatory access.

2.8.4.5. Use for Risk-Based Surveillance

Rwanda FDA may use the remote viewing system:

- As part of risk-based inspection and surveillance strategies
- To complement or reduce the frequency of physical inspections
- To investigate suspected diversion, misuse, or non-compliance

2.8.4.6. Enforcement Measures

Where a licensed person fails to install or maintain the required system, or obstructs access to the Authority, Rwanda FDA may apply enforcement actions, including:

- Suspension or revocation of the license
- Administrative penalties
- Increased inspection frequency

2.9. DENATURING OF ETHYL ALCOHOL

2.9.1 Mandatory denaturing requirement

2.9. 1.1 General Principle

Denatured alcohol is an alcohol made unsuitable for human consumption by adding a suitable chemical marker, very bad tasting and /or smelling products through a process of denaturation. Specific regulatory measures are required on different types of denatured ethyl alcohol to prevent fraud, misuse and protect consumers from various health risks.

2.9.1.2 Exemptions

1. Rwanda FDA may, at its sole discretion, grant a written exemption on the use of denatured ethyl alcohol if the applicant demonstrates a legitimate industrial or technical need;

2. Exemption shall only be considered when:

   a) The applicant provides an acceptable justification, supported by technical documentation, establishing that denaturation would provide the ethanol unsuitable for its intended industrial application;
   b) The applicant demonstrates that robust, verifiable security and diversion-control measures are in place and have been effectively implemented throughout the supply chain;

c) A comprehensive risk assessment conducted by Rwanda FDA concludes that the exemption does not present an unacceptable risk to public health or safety.

3. Any exemption granted shall be in writing, specify the exact quantities and grades of non-denatured ethanol authorized, be subject to specific conditions, and remain valid for a defined period.

4. The possession, distribution, or use of non-denatured industrial ethanol without a valid written exemption from Rwanda FDA shall be considered a serious regulatory violation. Such ethanol shall be subject to immediate seizure, forfeiture, and administrative sanctions, including but not limited to suspension or revocation of licenses and the imposition of applicable fines.

2.9.2. Classes of denatured alcohol and formulas/formulations

(1) For the purpose of these Regulations, three classes of denatured alcohol are considered:

a. Completely denatured alcohol
b. Industrial denatured alcohol
c. Trade specific denatured alcohol

(2) Completely denatured alcohol is the alcohol which has been completely denatured with toxic substances to make it unfit for human consumption and medical uses. These formulations ensure that the alcohol remains useful for general use such as laboratory solvents, cleaning agents, and fuel while being unsafe for human consumption.

(3) Industrial denatured alcohol is the alcohol partially denatured with substances to make it fit for industrial general purpose. Substances used in the formulation are incorporated into a product that is not for human consumption.

(4) Trade specific denatured alcohol is the alcohol denatured with a specific formulation tailored for a particular industry and application. Trade specific denatured alcohol formulations are types of denatured alcohol approved to meet specific trade needs.

(5) Different types of formulations are available at national and international levels (see appendix XXX).

(6) These classes of denatured alcohol are based on the intended uses and have different formulations.

(7) The application for denaturing alcohol must include:

i. Class of denatured alcohol which the manufacturer intends to produce.
ii. Formulations which the manufacturer intends to follow in making batch of that class.
iii. Process which the manufacturer intends to employ when mixing the alcohol with other substances in producing the denatured alcohol.
iv. Certificates of analysis of the final denatured alcohol.
v. Intended use of the final denatured alcohol.
vi. Shall submit a sample of the final denatured alcohol to the Rwanda FDA in order to determine whether the product has been properly denatured according to the requirements.

(8) Release of denatured alcohol for use and distribution

i. The applicant should submit the certificate of analysis/test report to Rwanda FDA prior to any removal from the premises, warehouse, delivery or distribution of the denatured alcohol.

ii. In order to receive the certificate of analysis/test report, the applicant should submit a sample (**(7), vi**) to Rwanda FDA. Rwanda FDA shall check the sample of denatured alcohol and issue the feedback letter to the applicant.

2.9.3 Denaturing formulas and technical specifications

2.9.3.1. Authorization of formulas/formulation

1. Approved denaturing formulas shall be aligned with national and internationally recognized standards, including but not limited to those developed or referenced by the World Health Organization (WHO), and relevant national or international pharmacopoeias such as USP, BP, etc..

2. Denaturing shall be conducted strictly in accordance with formulas/formulation that have been formally approved in writing by Rwanda FDA.

2.9.3.2. Categories of approved denaturants

Denaturation of alcohol may be done and approved through the addition of one or more of the following substances:

- Chemical analytical marker: Tert-butyl alcohol, isopropyl alcohol, methyl isobutyl ketones and diethyl phthalate, etc … are chosen as they are most difficult to remove through distillation or other processes to reverse the denaturation.

- Smelling agent(s): methyl ethyl ketones, methyl isobutyl ketones, etc.

- Tasting agents, bittering substances such as denatonium benzoate (the most commonly used).

- Coloring agents, dyes for visual identification.

- Other additives: methanol, essential oils, complexing agents, water, etc. can be used depending on the classes of denatured alcohol.

2.9.3.3. Efficacy criteria for denaturing

The addition of approved denaturants must demonstrably achieve the following objectives:

i. Provide the alcohol permanently unfit for human consumption;
ii. Provide the alcohol organoleptically unpleasant, deterring casual or intentional ingestion;

iii. Provide the alcohol economically impractical to purify for beverage use, such that the cost of removing the denaturant exceeds the value of the reclaimed ethanol.

2.9.4. List of denaturants for the purpose of manufacturing denatured spirits

List of products	Chemical Abstracts Service (CAS) number
Acetone	67-64-1
Denatonium benzoate	3734-33-6
Ethanol	64-17-5
Ethyl tert-butyl ether	637-92-3
Fluorescein	2321-07-5
Gasoline (including unleaded gasoline)	86290-81-5
Isopropyl alcohol	67-63-0
Kerosene	8008-20-6
Lamp oil	64742-47-8 and 64742-48-9
Methanol	67-56-1
Methyl ethyl ketone (2-butanone)	78-93-3
Methyl isobutyl ketone	108-10-1
Methylene blue (52015)	61-73-4
Methyl violet dye (methylrosaniline chloride)	548-62-9
Solvent naphtha	92062-36-7
Kerosene petroleum oil (mineral naphtha	64742-94-5
Tertiary-Butyl alcohol	75-65-0
Sucrose octaacetate	126-14-7
Diethyl phthalate	84-66-2
Crude Pyridine	110-86-1
wood naphtha*	67-56-1
ethyl acetate	141-78-6
cyclohexane	110-82-7
hexane	110-54-3
benzyl benzoate	120-51-4
Ethyl isoamyl ketone	591-78-6
Methyl isopropyl ketone	563-80-4
Spirits of turpentine	8006-64-2
Technical petrol	92045-57-3

Note:

2.9.5. Quality

All substances used in the production of denatured alcohol must be of sufficient quality to ensure that the final product complies with the technical specifications.

2.9.6. Certificate of analysis/test report

The certificate of analysis/ test report should contain at least the following information:

i. Name, legal address, and legal document number
ii. Address of the premises
iii. Volume in litres of absolute ethanol of the declared denatured alcohol
iv. The alcohol denaturing substance(s) and related concentration in the product;
v. List of tested parameters, results, and technical specifications;
vi. Date of issue of the test report and approval by competent persons.

CHAPTER 3: REGISTRATION REQUIREMENTS

3.1 Introduction

An application for ethyl alcohol registration for either locally manufactured or imported shall be made in writing and supported by an official cover letter (Annex I) and application form available on Rwanda FDA website duly dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative (LTR). The LTR shall be a registered wholesale or importer or an accredited manufacturer's representative company registered in Rwanda.

All application documents shall be in one of the official languages used in Rwanda. Any document which is in any language other than the official languages must be accompanied by a certified or notarized document translated in official language.

An application for product registration is submitted as electronic documents and received through IRIMS available at https://irims.rwandafda.gov.rw/portal/#/public/app-home. The application is assessed through the system and the applicant is queried for any document that is not fulfilling the application requirements. The reference number assigned to the product during the application is used in all subsequent correspondences relating to the application. An acknowledged receipt of application will be issued by the system.

After receiving the product application, Rwanda FDA shall proceed with screening of the dossier for completeness. In the event that the dossier is incomplete, it will not be scheduled for assessment and the applicant will be notified within 30 calendar days and requested to comply with requirements in writing. In case of a positive outcome during the screening, the application will be scheduled for assessment according to the First in First out (FIFO) rules.

The submission of samples for registration shall be in the final package proposed for marketing of the product in Rwanda and shall have at least 60% of its shelf-life remaining. This notwithstanding, products with a shelf life of less than 24 months shall have at least 80% of its shelf life remaining at the time of submission. Two commercial samples must be directly submitted to Rwanda FDA headquarter on the addresses below:

Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali

Nyarutarama Plaza, KG 9 Avenue

The additional samples may be requested once deemed required during the registration process. Where it is not possible due to big pack size (above 5L), the applicant shall be requested to avail the necessary commercial sample size simulated and equivalent (1L) to the big commercial samples for further assessment procedures. The simulated and equivalent commercial samples shall never be placed on the market. A hard copy of the letter should be brought with samples for reception acknowledgement by Rwanda FDA.

3.2.Types of ethyl alcohol product applications for registration

For the purposes of submission of ethyl alcohol dossier to Rwanda FDA, applications are classified into three categories as follows:

3.2.1 New applications for registration

An application for registration of ethyl alcohol product that is intended to be placed on the Rwanda market for the first time or product which was on the market without a registration certificate.

3.2.2 Renewal application for registration

Applications for renewal of the marketing Authorization of ethyl alcohol that has been previously registered. The application dossier shall be submitted to the Rwanda FDA at least 3 months before the expiry of existing marketing Authorization Certificate.

3.2.3. Variation application

Variation application refers to the application for any change in the registered products. An application for variation shall be submitted as per the requirements set out in the Guidelines for Variations of Registered Cosmetics, Vector Control Products and Public Health Laboratory Chemical Products including ethyl alcohol.

The requirements for variation application are detailed in the Guidelines on Submission of Documentation for Variation of Registered Cosmetic, Vector Control and Public Health Laboratory Chemical Products (Doc. No.: DD/CHCR/GDL/005 Version 1).

3.3. GENERAL REQUIREMENTS FOR REGISTRATION

3.3.1. Requirements for locally manufactured ethyl alcohol

3.3.1.1 Section A: Administrative Requirements

All administrative documents should be provided in part of administrative requirements as follow:

3.3.1.1.1. Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I)

3.3.1.1.1. Application form

A dossier application must include a completed application form Nº: DD/CHCR/FORM/004 for new registration of Public Health Laboratory Chemical Products and which is available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

3.3.1.1.2. Manufacturing License

The applicant should have a manufacturing license issued by Rwanda Food and Drugs Authority for manufacturing ethyl alcohol.

3.3.1.1.3. Contract Manufacturing Agreement (where applicable)

An agreement between two parties (the party who manufactures ethyl alcohol per the order of another party) is required. If ethyl alcohol is manufactured on contract, evidence of the contract shall be included in the documentation submitted, and this shall be clearly stated on the label of ethyl alcohol.

3.3.1.1.4. Samples of ethyl alcohol

Two (2) samples of ethyl alcohol shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

3.3.1.1.5. One coloured artwork/ Label of ethyl alcohol

The applicant should submit one coloured artwork/ Label of ethyl alcohol.

3.3.1.2.Section B: Technical Requirements

3.3.1.2.1. Composition of each substance

a) Degree of purity
b) Nature of impurity (%),
c) Percentage of (significant) main impurities
d) Description of the analytical methods for the identification of impurities and determination of purity. This information shall be sufficient to allow the reproducibility of the used analytical methods.

3.3.1.2.2 Use of the product

a) Intended use(s)
b) Guidance on safe use

3.3.1.2.3 Labelling information

Ethyl alcohol manufacturers, importers, or distributors must ensure that each container of this product is labelled, tagged or marked with the following information:

a) Name, address of the manufacturer, or responsible party.
b) Product name
c) Manufacturing date and Expiry date
d) Net content (weight/volume)
e) Purity/concentration
f) Density (if applicable)
g) Lot or batch number
h) List of ingredients used (if applicable)
i) Instructions for use
j) Storage conditions
k) Country of origin

3.3.1.2.4 Hazard and safety information

Ethyl alcohol manufacturers, importers, or distributors must ensure that each container of ethyl alcohol is labelled, tagged or marked with the following information related to hazard:

a) Product identifier
b) Signal word and hazard symbol
c) In case your ethyl alcohol displays a more severe hazard, the label should bear the signal word "Danger", and in case of less severe hazards, it should bear the signal word "Warning"
d) Hazard statement(s)
e) Precautionary statement(s)
f) GHS pictogram(s)

3.3.1.2.5 Safety data sheet (SDS)

Applicant of registration of ethyl alcohol shall submit to Rwanda FDA a safety data sheet compiled according to the Global Harmonization System (GHS). The SDS to be submitted should contain the detailed information as required by the GHS for hazard communication standard. Specifically, the SDS containing the following sections is recommended:

Section 1. Product Identification: Brand name and chemical name
Section 2. Hazards identification and analysis
Section 3. Composition and information on ingredients
Section 4. First Aid Measure
Section 5. Firefighting measures

Section 6. Accidental release measures
Section 7. Handling and storage
Section 8. Exposure control/Personal protection
Section 9. Physical and chemical properties
Section 10. Stability and reactivity
Section 11. Toxicological information
Section 12. Ecological information
Section 13. Disposal information
Section 14. Transport information
Section 15. Regulatory information
Section 16. Other information

3.3.1.2.6 Certificate of analysis

The duly signed and dated certificate of analysis bearing its unique identification number, batch number, date of manufacturing and expiry date, tested parameters, specifications, methods and test results shall be submitted.

3.3.1.2.7 Composition of each substance

a) Degree of purity
b) Nature of impurity (%)
c) Percentage of (significant) main impurities
d) Spectral data (infra-red, nuclear magnetic resonance),
e) Elemental analysis data
f) Description of the analytical methods for the identification of impurities and determination of purity.

3.3.1.2.8 Commitment letters (if applicable)

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be availed. Rwanda FDA reserves its total rights to request the applicant to submit the commitment letter wherever needed.

3.3.2.1.Section A: Administrative requirements

3.3.2.1.1 Cover letter

Applicants shall include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I).

3.3.2.1.2 Application form

Dossier application must include a completed application form Nº: DD/CHCR/FORM/004 for new registration of Public Health Laboratory Chemical Products which is available on Rwanda FDA

website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

3.3.2.1.3 Valid Manufacturing license

The applicant shall also submit a valid certificate of public health laboratory chemical product manufacturing license granted by the competent authorities in the country of manufacturing.

3.3.2.1.4 Contract Manufacturing Agreement (if Applicable)

Once ethyl alcohol is manufactured under the manufacturing contract, evidence of the updated contract shall be produced in the submitted documentation. And this shall be clearly stated on ethyl alcohol label/artwork.

3.3.2.1.5 Valid GMP or other applicable internationally recognized Management System certification

For all foreign manufactured ethyl alcohol, all key manufacturing and/or processing steps in the production of finished ethyl alcohol must be performed in plants that comply with GMP or ISO. Regarding to the quality and safety concern of ethyl alcohol, applicant may be requested to apply for GMP inspection to Rwanda FDA.

3.3.2.1.5 Appointment of local technical representative

Appointment letter of the LTR with original copy of Power of attorney must be enclosed in the product dossier. The LTR shall be a wholesale or importer of cosmetics or household chemicals or pharmaceutical products licensed by Rwanda FDA or any manufacturer's representative company registered in Rwanda.

In case that LTR is not wholesale or importer of cosmetics or household chemicals or pharmaceutical products licensed by Rwanda FDA, a contract with a company with Rwanda FDA licensed premises for cosmetics or household chemicals or pharmaceutical products shall be submitted.

3.3.2.1.7 Samples of the ethyl alcohol

Two (2) samples of ethyl alcohol shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

3.3.2.1.8 One coloured artwork/Label of ethyl alcohol

The applicant should submit one coloured artwork/Label of ethyl alcohol.

3.3.2.1.9 Commitment letters (if applicable)

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be availed. Rwanda FDA reserves its total rights to request the applicant to submit the commitment letter wherever it is applicable.

3.3.2.2 Technical data requirements

3.3.2.2.1 Composition of each substance

a) Degree of purity
b) Nature of impurity (%), including isomers and by-products (if applicable)
c) Percentage of (significant) main impurities
d) Spectral data (infra-red, nuclear magnetic resonance), (ultra-violet, mass spectra if applicable)
e) HPLC, Gas Chromatography chromatogram (volatile compound) if applicable
f) Elemental analysis data
g) Description of the analytical methods for the identification of impurities and determination of purity. This information shall be sufficient to allow the reproducibility of the used analytical methods.

3.3.2.2.2. Uses of ethyl alcohol

a. Intended use(s)
b. Hazard classification of the substance

3.3.2.2.3 Labelling information

Ethyl alcohol manufacturers, importers, or distributors must ensure that each container of ethyl alcohol is labelled, tagged or marked with the following information:

a) Name, address of the manufacturer, or responsible party.
b) Product name
c) Manufacturing date and Expiry date
d) Net content (weight/volume)
e) Purity/concentration
f) Density (if applicable)
g) Lot or batch number
h) List of ingredients used
i) Instructions for use
j) Storage conditions
k) Country of origin

3.3.2.2.4 Hazard and safety information

a) Product identifier

b) Signal word and hazard symbol; In case your ethyl alcohol displays a more severe hazard, the label should bear the signal word "Danger", and in case of less severe hazards, it should bear the signal word "Warning"
c) Hazard statement(s);
d) Precautionary statement(s)
e) GHS pictogram(s)

3.3.2.2.5. Safety data sheet (SDS)

The applicant of registration of ethyl alcohol shall submit to Rwanda FDA a safety data sheet compiled according to the Global harmonization system. The SDS to be submitted should contain the detailed information as required by the Global harmonization system for hazard communication standard. Specifically, SDS containing the following sections is recommended:

Section 1. Product Identification: Brand name and chemical name
Section 2. Hazards identification and analysis
Section 3. Composition and information on ingredients
Section 4. First Aid Measure
Section 5. Firefighting measures
Section 6. Accidental release measures
Section 7. Handling and storage
Section 8. Exposure control/Personal protection
Section 9. Physical and chemical properties
Section 10. Stability and reactivity
Section 11. Toxicological information
Section 12. Ecological information
Section 13. Disposal information
Section 14. Transport information
Section 15. Regulatory information
Section 16. Other information

3.3.2.2.6 Certificate of analysis

The duly signed and dated certificate of analysis bearing its unique identification number, batch number, date of manufacturing and expiry date, tested parameters, specifications, methods and test results should be submitted.

3.3.2.2.7 Stability data

The proposed shelf life should be justified by submission of stability data. The applicant shall provide stability data supporting the proposed shelf life. The stability studies shall be conducted in the container in which it will be marketed in Rwanda. Stability study report critically examine the method used to determine the established product shelf life including:

1. Study design (protocol);

2. Test conditions (humidity and temperature), testing interval;
3. Duration:

Storage conditions	**Duration**	**Testing interval (Months)**
Long term stability studies at 25±5°C/60% RH	Shelf life	0, 3,6,9,12,18,24,36,48
Accelerated stability studies at 40°C/75% RH	6 months	0,3,6

4. Type of container used (Testing should be conducted using containers and closures intended for marketing of products);
5. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product.

3.4. General requirements for renewal of ethyl alcohol registration

An application for Market Authorization renewal shall be made ninety (90) calendar days before expiration of the last registration. Rwanda FDA foresees a grace period for renewal of ninety (90) days after the specified expiry date. Failure to renew the marketing authorization within the grace period, the application shall be considered as new.

3.4.1. Cover letter

Signed and dated cover letter addressed to the Director General of Rwanda FDA must be submitted.

3.4.2. Application form

Signed and dated application form No: DD/CHCR/FORM/006 for renew of registration of cosmetic, vector control products, public health antiseptic and disinfectant and public health laboratory chemical products shall be completed, and this form is available on Rwanda FDA website.

3.4.3 Copy of previous registration certificate

The applicant shall submit the copy of previous registration certificate issued by Rwanda FDA.

3.4.4 Supporting documentation for any variations since the ethyl alcohol was last registered

During the renewal of the ethyl alcohol, the applicant must submit the data for the variations that have been reported and also the variations which were not reported yet (variation that happened in the last year of certificate validity).

3.5. Ethyl alcohol Registration timelines

Product dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. For new applications, assessment process shall be processed within three (3) months from the date of submission, with feedback provided to the applicant. Regarding the

renewal application of the registered products, the assessment shall be processed within two (2) months from the date of submission, with feedback provided to the applicant. The applicant will be required to provide any requested additional data within six (6) months. Assessment of submitted additional data or query responses shall be processed within sixty (60) calendar days from the day of submission with feedback provided to the applicant.

Once a query has been issued to the applicant, the assessment process stops until Rwanda FDA receives a response to the raised queries. Further processing of the application may only be undertaken if responses to issued queries, contain all outstanding information requested in one submission. If the queries have been reissued for a third time and the applicant provides unsatisfactory responses, the application shall be rejected. In the event that the responses to the queries are not submitted within specified timeline from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested for extension of deadline to Rwanda FDA. Thereafter, registration of the product may only be considered upon submission of a new application.

CHAPTER 4: IMPORTATION AND EXPORTATION OF ETHYL ALCOHOL

4.1. Eligibility to import or export

1. Ethyl alcohol shall be imported or exported only by a Business O perator established in Rwanda who falls under at least one of the following categories:

i. Manufacturer (including denaturation) holding a valid operational/premises license for activities requiring ethyl alcohol as a raw material or processing aid (including industrial, cosmetic, pharmaceutical, medical, laboratory, and food-related uses, as applicable);
ii. A licensed wholesaler/distributor authorized to handle ethyl alcohol;
iii. A government institution;
iv. Research or educational institution;
v. Any other entity authorized by a competent authority for justified purposes.

The applicant shall hold a valid operational license/premises license, as applicable, issued a competent authority for the activity and facility where ethyl alcohol will be stored, handled, processed, or used.

4.2. General requirements

1. Ethyl alcohol shall be imported or exported only through officially designated points of entry and exit.
2. Each consignment of ethyl alcohol shall be subject to control measures, including documentary verification, physical inspection, and sampling/testing where required.
3. Importers and exporters shall ensure full traceability of ethyl alcohol consignments, including batch/lot traceability, storage locations, and distribution/use records.
4. For ethyl alcohol intended for use as a raw material**,** importation and exportation shall be restricted to supply chains compliant with Rwanda FDA registration and GMP requirements.

Note: Rwanda FDA may request any additional information deemed necessary to support regulatory decision-making.

PART A . IMPORTATION OF ETHYL ALCOHOL

4.3. Import authorization

1. Importation of ethyl alcohol shall be subject to an import license issued for a specific applicant and a particular consignment prior to its shipment to Rwanda.
2. An import license shall not be transferable.

4.4. Application for an import license

1. An application for an import license shall be submitted through IRIMS platform prescribed by Rwanda FDA, unless otherwise decided by the Rwanda FDA .
2. The applicant shall provide accurate and complete information and supporting documents for each consignment.
3. Rwanda FDA may approve, query, or reject the application, and the applicant shall be notified through the official platform or in writing where applicable.

4.5. Minimum documentary requirements for import license application

1. An application for an import license for ethyl alcohol shall be accompanied by the following documents, as applicable:

    i. Valid operational license/premises authorization relevant to handling and use of ethyl alcohol for the declared intended purpose;
    ii. Commercial invoice indicating supplier identity, importer identity, product description, batch/lot number(s), quantity, unit price, total value, and country of origin;
    iii. Certificate of analysis for each batch/lot indicating tested parameters, methods, results, batch/lot identification, and signature of an authorized person;
    iv. Certificate of compliance of the manufacturer for non-registered ethyl alcohol imported by government institutions and/or research/education organizations;
    v. Utilization and distribution report for previously imported ethyl alcohol.

The import license shall be subjected to applicable fees as prescribed in Rwanda FDA tariff/fees structure.

4.6. Product particulars to be declared in the application

The applicant shall declare, at minimum, the following particulars for each consignment:

i. Product name (ethyl alcohol/ethanol) and trade name, where applicable;

ii. Alcohol strength (% v/v) and grade/specification;
iii. Denatured or undenatured status and, where denatured, the denaturant/formula reference;
iv. Batch/lot number(s);
v. Manufacturing date and expiry/retest date, where applicable;
vi. Packaging type and net content per package;
vii. Total quantity and number of packages;
viii. Manufacturer name and country of origin; supplier name and country of supply;
ix. Intended use and destination facility where the product will be stored/used;
x. Any other information required by Rwanda FDA.

4.7 . Renewal of an import license

1. Where an import license expires before it is used, or where it is partially used and expires before completion of importation of the approved quantity, the applicant shall apply for renewal through the official platform or in any other way prescribed by the Authority.

2. An application for renewal shall be accompanied by the following documents, as applicable:

    a) An application letter/request for renewal;
    b) Valid operational license/premises authorization relevant to handling and use of ethyl alcohol;
    c) Commercial invoice for the consignment,
    d) The expired import license;
    e) Confirmation by Rwanda FDA mandate official of the remaining quantity, where applicable;
    f) Proof of payment of applicable fees, where applicable
    g) Utilization and distribution report for previously imported ethyl alcohol.

4.8. Inspection and control at the point of entry

1. Upon arrival of the consignment at the point of entry, the importer shall notify Rwanda FDA for inspection in accordance with established procedures.
2. Rwanda FDA shall verify compliance through documentary verification and physical inspection of the consignment.
3. Rwanda FDA may take samples for laboratory testing based on risk, intended use, or suspicion of non-compliance.
4. A consignment may be held under quarantine pending test results, investigation, or completion of inspection requirements.
5. Where non-compliance is confirmed, the consignment shall be rejected and be handled in accordance with applicable procedures, including:
6.

    i. Re-export;
    ii. Safe Disposal; or
    iii. Any other measure approved by Rwanda FDA.

4.9. Post-import accountability and utilization reporting

1. Importers of ethyl alcohol shall maintain stock , distribution, and use records to ensure full traceability.
2. Before issuance of a subsequent import license, Rwanda FDA shall require submission of a usage and distribution report for previously imported ethyl alcohol.
3. The report shall include at minimum:
   i. Import license reference(s);
   ii. Batch/lot traceability;
   iii. Quantities imported and remaining;
   iv. Quantity used
   v. Distribution destinations/recipients, where applicable; and
   vi. Declared use categories.

4.10. Marking and identification for control and traceability

Each imported consignment and/or immediate container of ethyl alcohol, as applicable, shall bear identification marks sufficient to support inspection and traceability, including at minimum:

a) Product identification (ethyl alcohol/ethanol or Neutral Spirit);
b) Manufacturer identity
c) Batch/lot number;
d) Alcohol strength;
e) Net quantity;
f) M anufacturing date and expiry/retest date, where applicable;
g) Undenatured, Denatured status and denaturant identification where applicable;
h) Storage/handling precautions and use restrictions, where applicable.

PART B: EXPORTATION OF ETHYL ALCOHOL

4.11. Export authorization

1. Exportation of ethyl alcohol shall be subject to an export license, where required by the destination country and/or as determined by Rwanda FDA.
2. Export authorization shall be issued to a specific applicant and a particular consignment and shall not be transferable.

4.12. Application and minimum documentary requirements for export authorization

An application for export authorization shall be submitted through the official platform prescribed by Rwanda FDA and shall include, as applicable:

i. Valid operational license/premises authorization relevant to handling and export of ethyl alcohol;
ii. Commercial invoice indicating exporter identity, consignee identity, product description, batch/lot number(s), quantity, unit price, total value, and destination;
iii. Certificate of analysis for each batch/lot;
iv. Evidence of any destination-country requirement for an export certificate/license, where applicable.

4.13. Renewal of an export license

1. Where an export license expires before it is used, the applicant shall apply for renewal through the official platform or in a manner prescribed by Rwanda FDA .
2. An application for renewal shall be accompanied by the following documents, as applicable:

i. The expired export license/authorization
ii. Commercial invoice;
iii. Confirmation by Rwanda FDA mandate official of the remaining quantity, where applicable;

4.14. Inspection at the point of exit

1. The exporter shall notify Rwanda FDA for inspection prior to export at the point of exit or at owner's premises to conduct documents verification, and physical inspection .
2. A consignment shall be authorized for export only where compliance is confirmed.

CHAPTER 5. SAFETY MONITORING AND MARKET SURVEILLANCE OF ETHYL ALCOHOL

Safety monitoring shall apply to manufacturers, importers, exporters, distributors, repackers, storage facilities, transporters, and end-users handling ethyl alcohol for industrial, laboratory, medical, food or pharmaceutical purposes.

5.1. Powers of Entry and Inspection

1. For purposes of safety monitoring and market surveillance, a duly mandated inspector of Rwanda FDA may, at any reasonable time and where public health risk is suspected, at any time enter any premises where activities involving ethyl alcohol are conducted.

Such premises include but are not limited to:

- Manufacturing facilities
- Warehouses and storage depots
- Distribution centers
- Import/export storage points
- Transport vessels

- Laboratories

3. During an inspection, the inspection team may:

- Examine raw materials, semi-finished, and finished products ;
- Inspect processing equipment, storage tanks, pipelines, and packaging lines;
- Review production processes and standard operating procedures (SOPs);
- Verify calibration and maintenance records of critical equipment;
- Examine quality control documentation and laboratory results;
- Review stock registers, batch records, and distribution logs;
- Conduct inventory reconciliation;
- Take measurements, samples, and photographs;
- Make copies of records relevant to compliance;
- Conduct stock-taking and physical verification against declared quantities.

4. Inspectors may also assess fire safety systems, ventilation, segregation of denatured and non-denatured alcohol, and security controls intended to prevent diversion.

5.2. Sampling and laboratory testing

Where deemed necessary, inspectors may collect samples of:

- Non-denatured ethyl alcohol;
- Denatured alcohol;
- Semi-finished products;
- Finished products containing ethanol;
- Raw materials used in ethanol production.

Samples shall be sealed, labeled, and documented in accordance with official sampling procedures.

Laboratory analysis may include testing for:

- Ethanol content ;
- Methanol content;
- Presence of unauthorized denaturants;
- Impurity profile (e.g., acetaldehyde, fuel oils);
- Contaminants or adulterants.

Pending laboratory results, Rwanda FDA may impose precautionary control measures.

5.3. Seizure and Quarantine

1. Where ethyl alcohol or related products are suspected to be:

- Substandard;
- Adulterated;
- Contaminated (including methanol contamination);

- Improperly denatured;
- Mislabeled;
- Diverted from approved use;
- Imported or manufactured without authorization;

The inspection team may detain, or quarantine such products pending further investigation.

Quarantine shall be documented through an official notice indicating:

- Description and quantity of the product;
- Reason for detention;
- Location of storage;
- Regulatory basis for action;
- Rights and obligations of the owner.

Quarantined products shall not be moved, altered, or disposed of without written authorization from Rwanda FDA .

If laboratory analysis confirms non-compliance, Rwanda FDA may order:

- Recall;
- Reprocessing (if appropriate);
- Destruction under supervision;
- Administrative sanctions.

5.4. Obligations of the Premises Owner or Responsible Person

1. The owner, manager, or person in charge of the premises shall provide full cooperation to the inspector.
2. The responsible person shall:

- Grant unrestricted access to all relevant areas of the premises;
- Provide requested documents, records, and data without delay;
- Facilitate sampling and stock verification;
- Ensure availability of competent staff to explain processes;
- Provide protective equipment for safety where required .

Obstruction, refusal of entry, concealment of records, or provision of false information constitutes a regulatory offense and may result in enforcement action.

5.5. Control Measures and Risk Mitigation Actions

Where there is reasonable evidence or suspicion that ethyl alcohol presents a risk to public health or safety, Rwanda FDA may implement control measures including but not limited to:

- Temporary closure of the premises;
- Suspension of manufacturing or distribution activities;

- Suspension or revocation of license;
- Restriction of specific operations;
- Mandatory product recall;
- Mandatory corrective actions and preventive actions (CAPA);
- Public safety alerts, where necessary.

Control measures shall be proportionate to the level of risk identified and shall aim to prevent further distribution or propagation of suspected substandard or hazardous alcohol.

5.6. Re-opening and Resumption of Operations

1. Where Rwanda FDA has imposed temporary closure, license suspension, or any restrictive control measure, the affected entity shall not resume operations without prior written approval from Rwanda FDA .
2. Before re-opening or resuming activities, the owner shall:

    - Implement all corrective actions required by Rwanda FDA;
    - Submit evidence of compliance;
    - Undergo follow-up inspection where applicable;
    - Demonstrate elimination of identified risks.
3. Operating without written approval following suspension or closure shall constitute a serious violation subject to sanctions.

5.7. Documentation and Reporting

All inspections and enforcement actions shall be:

- Documented in official inspection reports;
- Classified according to severity of non-compliance status (critical, major, minor);
- Communicated formally to the concerned entity;
- Recorded in the Rwanda FDA 's safety monitoring database.

Where public health risk is confirmed, relevant enforcement bodies and other competent authorities may be notified.

5.8. Coordination with Other Authorities

For effective safety monitoring and diversion control, Rwanda FDA may collaborate with:

- Law enforcement agencies;
- Customs authorities;
- Standards bodies;
- Security Organs

Joint inspections may be conducted where necessary to address risks related to illicit production, or hazardous chemical handling.

5.9. Enforcement and Penalties

Non-compliance identified through safety monitoring may result in:

- Written warnings;
- Administrative fines;
- Suspension or revocation of licenses;
- Quarantine and destruction of products;
- Referral for criminal investigation where applicable.

ENDORSEMENT OF THE GUIDELINES

	Author	**Checked by**		**Approved by**
Title	**Division Manager**	**Head of Department**	**Division Manager/QMS**	**Director General**
Names				Dr. Emile BIENVENU
Signature				
Date				

APPENDICES

APPENDIX I: APPLICATION FORM

Format: Revision No: Effective Date:		Department/Division	Drugs /Pharmaceutical inspections and licensing
Document Type: **Form**			Doc. No :
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application Form for Premise Licensing of Ethyl alcohol**		Revision Number : 0
			Revision Date: :
			Effective Date :
			Review Due Date :
			Ref Doc. :

Name of Premise (Company):
……
……

Application date: / /
DD / MM/ YYYY

Domestic Company Registration code (TIN):
……

Premise Registration Certificate Number (Issued by Rwanda FDA):
……
…

Physical location:
(Province, District, Sector, Cell, Village)
……
……
……

Company e-mail:
……
…

Global Positioning System (GPS) Coordinates
……
……

Company Telephone:
……
…

Name of the authorized person :
(If applicable)
……
……

Name of Managing Director:
……
…
……
…

Email of the authorized person :
(if applicable)
……
……
……

Email of Managing Director
……
…

Telephone of the authorized person:
……
…
……
…

Telephone of the managing Director:
……
…
……
…

TYPE OF PREMISE:
(Please tick below)

- ☐ Retailer
- ☐ Wholesaler
- ☐ Distributor
- ☐ Manufacturer
- ☐Other (Please Specify) ……..……

MAIN ACTIVITY
(Please tick below)

- ☐ Retailer of Ethyl alcohol
- ☐Wholesaler of Ethyl alcohol
- ☐Distributor of Ethyl alcohol
- ☐ Manufacturer of Ethyl alcohol
- ☐ Other (specify) ……..……

TYPE OF APPLICATIONS
(Please tick below)

- ☐ Site location approval
- ☐ New Application (Premise Registration & Licensing
- ☐ License Renewal
- ☐ Relocation or additional storage space of the licensed premise
- ☐ Change of the authorized technician
- ☐ Change of the ownership
- ☐ Change the name of the license premise
- ☐ *Closure of the business activities*
- ☐ Re-inspection
- ☐Other specify ……..…

AFFIDAVIT

I hereby affirm that the statement in this application is true and correct.

Applicant's Name and Signature _____ **Date (dd/mm/yyyy)** _____

INSTRUCTION FOR APPLICANT:

1. *Ensure that **ALL** sections of the application form are fully completed before submission.*
2. *Incomplete application form **WILL NOT** be accepted.*

3. *Application processes will take 30 working days upon receipt of fully complete documents required.*
4. *All applications shall be valid for a period of ninety (90) calendar days from the date of application. When applicants failed to comply with the requirement (s) within ninety (90) calendar days' period, they shall re-apply and the prescribed premise licensing fees shall be paid.*

Application form for new registration of ethyl alcohol

1.	**ADMINISTRATIVE INFORMATION**
1.1	**Name(s) and complete physical address(es) of the manufacturer(s)** Company name: …… Physical address: ……. Postal address: ……. Country: ……... Telephone: ……... Telefax: ……... Email: ……....
1.2	**Particulars of Applicant/ Registrant** Name: …… Physical Address: ……. Postal Address: ……. Country: …… Phone: ……. Fax: ……. Email: ……. Status of applicant (tick where appropriate): Manufacturer: Importer: Exporter: Other:
1.3	**Particulars of Local Technical Representative/ Distributor (if applicable)** Name: …….. Physical Address: …… Postal Address: …… Country: …… Phone: …….. Fax:……. Email:……
1.4	**Marketing Authorisation in the country of manufacture of the ethyl alcohol** Authorised Country: ……. Date of authorisation (ddmmyyyy): …… Authorisation number: …… If not registered/licensed state reasons: …… Date of refusal (ddmmyyyy): …….... Reason for Refusal: ……

1.5	**Marketing Authorisation in the country of manufacture of ethyl alcohol withdrawn by applicant after authorisation** Withdrawn Country: …… Date of withdrawal: (ddmmyyyy): …… Reason for withdrawal: ……
	Marketing Authorisation in the country of manufacture of ethyl alcohol Suspended/revoked/banned by competent authority Country: …… Date of suspension/revocation/ban (ddmmyyyy): …… Reason for suspension/revocation/ban: ……..
1.6	**Class of ethyl alcohol**

Hazard Class and category	**Specify**
Acute toxicity, category 1,2, and 3	
Acute toxicity, category 4	
Skin corrosion/irritation, category 1, sub-categories: 1A, 1B, 1C and Category 2	
category 1: Sub-category: 1A…., 1B….., 1C….	
Category 2	
Serious damage to eyes/eye irritation, category 1 and 2	
Category 1	
Category 2	
Respiratory/skin sensitization	
Germ cell mutagenicity category 1A and 1B	
category 1A	
category 1B	
Germ cell mutagenicity category 2	
Carcinogenicity category 1A, 1B and 2	
category 1A	
category 1B	
category 2	
Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation	
category 1A	
category 1B	
category 2	
Specific target organ toxicity (STOT)-Single exposure, category 1 and 2	
category 1	
category 2	
Specific target organ toxicity (STOT)-Repeated exposure, category 1 and 2	
category 1	
category 2	
Aspiration Hazard	
Hazardous to the aquatic environment-Acute, category 1	
Hazardous to the aquatic environment-Chronic, category 1	

	Hazardous to the aquatic environment-Chronic, category 1, 2,3 and 4	
	category 1	
	category 2	
	category 3	
	category 4	
	Hazardous for the ozone layer	

1.7	Packaging material type:
1.8	Intended use:
1.9	Pack size:
1.10	Visual description:
1.11	Proposed shelf life:
1.12	Proposed shelf life (dilution if any):
1.13	Proposed shelf life (after first opening container):
1.14	Proposed storage conditions:
1.15	Proposed storage conditions after first opening:
1.16	Other sister products registered or applied for registration
1.17	Distribution category: ☐ Institutional ☐ Industrial ☐ General public. ☐ Other……
1.18	Country of (origin) manufacture:

1.19 Qualitative and Quantitative composition (chemical substance (s) and excipient(s)

No	Name of ingredient	Quantity/unit (ml, g)/ batch	Reasons of inclusion	Manufacturer and/or Supplier's full address
1				
2				
3				
4				
	Etc			

1.20	Submitted Spectral data (if applicable): Ultra-violet: **Yes** ☐ **No** ☐ Infra-red: **Yes** ☐ **No** ☐ Nuclear magnetic resonance: **Yes** ☐ **No** ☐ Mass spectrum: **Yes** ☐ **No** ☐
1.21	Do you hold Marketing Authorization (s) of this product from other regulatory authorities? **Yes** ¨ **No** ¨ If yes state; Market Authorization Number: Market Authorization issuance date: Name of Regulatory Authority issued the Market Authorization: Country:

2. LABELLING INFORMATION

2.1. Brief description of the type and properties of packaging material and the seal and its liner (if any) and

provide justification for the suitability of the packaging material and the seal and its liner used.
……
……
2.2. Recommended storage conditions (where applicable) including any relevant information after the product is opened for use or reconstituted:
……
……
2.3.Mode of
use ……
……

3. Declaration by the Applicant/ Registrant

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to Rwanda Food and Drugs Authority.

It is hereby confirmed that fees have been paid according to the Rwanda Food and Drugs Authority fees and regulation.

I understand that if any information given here above is found false or incorrect, I will be reliable for appropriate action under the provisions of the Rwanda Food and Drugs Authority regulation.

Name: ……
Position in the company: ……
Signature: ……
Official stamp: …….
Date: …….

APPENDIX II: LIST OF FORMATS USED WITH THESE GUIDELINES

1) Format of the manufacturing license for Ethyl alcohol (Doc. No. **……**)

RWANDA FDA
Rwanda Food and Drugs Authority

Doc Nº: DD/PIL/FMT/002
Version: 4
Effective Date: 01/03/2026

Manufacturing License Nº: ***Application Reference Number-0000***

MANUFACTURING LICENSE FOR [PRODUCT CATEGORY]

Pursuant to the Law Nº. 003/2028 of 09/02/2028 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, especially in its article 9 (2);

Rwanda FDA hereby authorizes the company whose details are listed below to operate **as a Manufacturer of [Product Category (Ethyl alcohol, etc…)]** following compliance with Good Manufacturing Practices (GMP) inspections, and having met marketing authorization requirements for the product(s) as detailed in Annex 1.

(a) Company details:

- **Company Name:**
- **Managing Director:**
- **Telephone number:**
- **Premises registration number:**
- **Location of the premises**: …. Province, …. District, ……. Sector, …… Cell, …….. Village

(b) Product details:

Product category	**Dosage form**	**Manufacturing activities**

(c) Company contact person details:

- **Names of the Managing Director:**
- **Telephone number:**

(d) Authorized person details:

- **Head of production names:**
- **Telephone number:**

Validity**: Five (5) years** from the date of approval.

Name, signature, date and stamp
Director General

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

Important notice

1. This license must be prominently displayed in the premises to which it refers;
2. This license is not transferrable and its misuse will result into suspension or revocation;
3. All changes to the product(s) must be communicated to the Authority within the framework of the relevant provisions of the applicable guidelines.
4. The responsibility for the quality and safety of the product(s)distributed under this license lies with the license holder and/or local technical representative;
5. This license is valid for five (5) years from the date of approval unless otherwise revoked or suspended by the Authority;
6. The validity for product registration is 5 years from the date of approval.
7. The license holder shall ensure that the application for renewal of this license is made 90 days before its expiration.
8. Registered products cannot be advertised/promoted or imported without prior approval of the Authority;
9. The product shall comply with all relevant provisions of Rwanda FDA regulations at all times;
10. The Authority reserves the right to withdraw this license when conditions under which it was provided are contravened and when the risks of using this license outweigh the benefits or it is in the public interest to do so.

Doc N°: DD/PH /FMT/002
Version: 4
Effective Date: 01/03/2026

RWANDA FDA
Rwanda Food and Drugs Authority

Annex I: List of approved products to LICENSE №: *RWA-FDA/DD-HRP/MM-YYYY/App. №/Lic №/*

Product Name	Product Category	Pack Size and Packaging Type	Manufacturer and Address	Marketing Authorization Holder (MAH)/Registrant	Product Registration Number	Date of Product Registration	Product Registration expiry date

Note: License Annex is issued in replacement of the previous annex under reference No:[……] dated [DD/MM/YYYY]. The former document is hereby declared no longer valid.

Name, signature and stamp
Director General

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

2) Format of premises registration certificate

RWANDA FDA
Rwanda Food and Drugs Authority

Doc Nº: ODG/QMS/FMT/025
Version:2
Effective Date: 14/10/2024

Premises Registration Nº: *RWA-FDA/DD-**Initial of Premise category/MM-YYYY/App.Nº/Reg. Nº***

PREMISES REGISTRATION CERTIFICATE

Pursuant to Law Nº 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, especially in its article 9 (2);

Rwanda FDA hereby issues this Premises Registration Certificate to **[PREMISES NAME]** under the management of **[Mr/Ms/Miss NAMES]** located in [Province], [District], [Sector], [Cell], [Village] as **[PREMISES CATEGORY FOR PRODUCT CATEGORY].**

Important notice:

1. *Any change in the ownership, name and location of the registered premises shall be approved by the Authority;*
2. *This certificate is not transferable to other premises or any other person and shall be displayed conspicuously in the registered premises;*
3. *The certificate shall only be used to operate business related to products approved by Rwanda FDA;*
4. *The certificate does not replace the premises license.*

Issued on / /

Names, Signature and Stamp
Director General

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

3) Format of the license to operate a Distributor/Wholesale/Retail of Ethyl alcohol (Doc. No ……..)

RWANDA FDA
Rwanda Food and Drugs Authority

Doc Nº: DD/PIL/FMT/004
Version: 5
Effective Date:01/03/2026

Premises License Nº: ***Application Reference Number-0000***

PREMISES LICENSE
FOR A [Distributor/ Wholesaler/ Retailer of Ethyl alcohol]

Pursuant to Law Nº 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, especially in its article 9 (2);

Rwanda FDA hereby authorizes the company identified below to operate as a **[Distributor/ Wholesaler/ Retail of ethyl alcohol, etc…],** following compliance with [**premises suitability inspection / Good Storage and Distribution Practices (GSDP) inspection**] and having met licensing requirements.

(a) Company details:

- **Company Name:**
- **Premises registration number**:
- **Location of the premises (sales):** …. Province, …. District, ……. Sector, …… Cell, …… Village
  - Store room 1: …. Province, …. District, ……. Sector, …… Cell, …… Village
  - Store room 2: …. Province, …. District, ……. Sector, …… Cell, …… Village

(b) Product details:

Nº	Product Category	Activities
1.		e.g: Storage, Dispensing, Distribution, Wholesaling,
2.		

(c) Company contact person details:

- **Names of the Managing Director:**
- **Telephone number:**

(d) Authorized person details:

- **Names of the authorized person:**

Page **1** of **3**

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

- **Professional Council Registration N°:**
- **Telephone number:**

Validity**: Five (5) years** from the date of approval

Name, signature, date and stamp
Director General

Important notice

1. This license must be prominently displayed in the premises to which it refers;
2. This license is not transferrable and its misuse will result into suspension or revocation;
3. All changes to this license must be communicated to the Authority within the framework of the relevant provisions of the applicable guidelines.
4. The responsibility for the quality and safety of the products distributed under this license lies with the license holder and/or authorized person;
5. This license is valid for five (5) years from the date of approval unless otherwise revoked or suspended by the Authority;
6. The license holder shall ensure that the application for renewal of this license is made two (2) months before its expiration.
7. Authorized products under this license cannot be advertised/promoted or imported without prior approval of Rwanda FDA;
8. Rwanda FDA reserves the right to withdraw this license when conditions under which it was provided are contravened and when the risks of using this license outweigh the benefits, or it is in the public interest to do so.
9. The authorized person shall be consistently present during operational hours of the licensed premises.

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

RWANDA FDA
Rwanda Food and Drugs Authority

Doc Nº: DD/PIL/FMT/004
Version: 5
Effective Date:01/03/2026

Annex: List of approved products to LICENSE Nº: *RWA-FDA/DD-HRP/MM-YYYY/App. Nº/Lic Nº/*

Product Name	Product Category	Pack Size and Packaging Type	Manufacturer and Address	Marketing Authorization Holder (MAH)/Registrant	Product Registration Number	Date of Product Registration	Product Registration expiry date

Note: License Annex is issued in replacement of the previous annex under reference No:[……] dated [DD/MM/YYYY]. The former document is hereby declared no longer valid.

Name, signature and stamp
Director General

Page **3** of **3**

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

4) Format of the ethyl alcohol Marketing Authorization

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/CHCR/FMT/007
Version:2
Effective Date: 14/10/2024

Certificate N°: *RWA-FDA/DD-EtOH-MA/ MM-YYYY/App. №/Reg.№*

MARKETING AUTHORIZATION CERTIFICATE
For
ETHYL ALCOHOL

With reference to the Law N°. 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning, especially in its article 9 (2);

Rwanda FDA hereby issues a marketing authorization certificate for the ***ETHYL ALCOHOL*** described below:

Trade/Brand Name: []

Name of the Active Ingredient(s) and Strength: []

Intended use: []

Pack size and Packaging type: []

Shelf life in months: []

Storage Statement: []

Name and address of the Marketing Authorization Holder: []

Name and address of Manufacturer: []

Name of Local Technical Representative: []

Validity: **Five (5)** years period from the date of approval

Names, Signature and Stamp
Director General

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707

Important notice

1. All changes to this product must be communicated to the Authority within the framework of the relevant provisions of the applicable guidelines.

2. This certificate is valid for five (5) years from the date of approval unless otherwise revoked or suspended by the Authority.

3. The Marketing Authorization Holder shall ensure that the application for renewal of this marketing authorization is made 90 days before, its expiration. Otherwise, the product shall be removed from the register.

4. Registered products cannot be advertised or imported without prior approval of the Authority.

5. The product shall comply with all relevant provisions of Rwanda FDA regulations at all times.

6. The Authority reserves the right to withdraw this certificate when conditions under which it was provided are contravened and when the risks of using this product outweigh the benefits or it is in public interest to do so.

Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: info@rwandafda.gov.rw
Website: www.rwandafda.gov.rw, Toll Free:9707