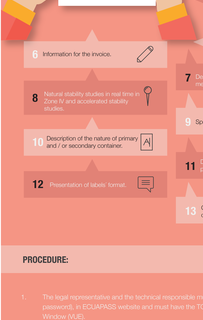
CERTIFICATES ISSUED BY THE NATIONAL AGENCY FOR REGULATION, CONTROL AND HEALTH SURVEILLANCE (Agencia Nacional de Regulación, Control y Vigilancia - ARCSA in Spanish)

HEALTH REGISTRATION AND RE-REGISTRATION OF DRUGS (LOCALLY MANUFACTURED)

DESCRIPTION:

In order to obtain for the first time the Health Registration for locally produced drugs, the manufacturer or legal representative shall submit through the Ecuadorian Single Window an individual application for each pharmaceutical form and concentration of the active principles.

REQUIREMENTS:



1. Request presented through the Ecuadorian Single Window (Ventanilla Unica Ecuatoriana - VUE in Spanish).
2. Duly authenticated original authorization of the holder of the product.
3. Notarized copy of the authorization, duly authenticated power or contract for manufacturing the product by a national laboratory, when the holder is another lab.
4. Original of the authorization of the product holder for the use of relevant technical documentation.
5. Interpretation of the batch code.
6. Information for the invoice.
7. Description of the analytical methods.
8. Natural stability studies in real time in Zone IV and accelerated stability studies.
9. Specifications of the finished product.
10. Description of the nature of primary and / or secondary container.
11. Description of the manufacturing process.
12. Presentation of labels' format.
13. Current pharmacological and clinical documentation in Spanish.

PROCEDURE:

1. The legal representative and the technical responsible must get his/her identification (username and password), in ECUAPASS website and must have the TOKEN to access the Ecuadorian Single Window (VUE).
2. Access the website of the VUE and submit the application and other requirements for obtaining the health registration of drugs.
3. Application review.
4. Rectification of the application.
5. Electronic payment.
6. Printing / Deplay of the Health Registry Certificate.

More information:
http://www.controlsanitario.gob.ec/inscripcion-de-registro-sanitario-de-medicamentos-fabricacion-nacional/

HEALTH REGISTRATION OF DRUGS (FOREIGN MANUFACTURED)

DESCRIPTION:

In order to obtain for the first time the Health Registration for foreign production drugs, the manufacturer or legal representative will present through the Ecuadorian Single Window an individual application for each pharmaceutical form and concentration of the active principles.

REQUIREMENTS:

1. Request presented through the Ecuadorian Single Window (Ventanilla Unica Ecuatoriana - VUE in Spanish).
2. Duly authenticated original authorization of the holder of the product.
3. "Pharmaceutical product certificate subject of international trade" according to WHO Model or "Free Sale Certificate" issued by the competent health authority of the country of origin of the product.
4. Original of the authorization duly legalized by the product holder.
5. Original of the authorization of the holder of the product for the use of the technical documentation that is required.
6. Interpretation of the batch code.
7. Information for the invoice.
8. Description of the analytical methods.
9. Natural stability studies in real time in Zone IV and accelerated stability studies.
10. Specifications of the finished product.
11. Description of the nature of primary and / or secondary container.
12. Description of the manufacturing process.
13. Presentation of labels' format.
14. Current pharmacological and clinical documentation in Spanish.

STANDARIZATION OF THE HEALTH CERTIFICATE OF DRUGS:

1. Request presented through the Ecuadorian Single Window (VUE).
2. Notarized copy of the Health Registration Certificate.
3. Notarized copy of the current "Pharmaceutical product certificate subject of international trade."
4. The leaflet for the user.
5. Duly legalized authorization by the product holder.
6. Information for the invoice.

PROCEDURE:

1. The legal representative and the technical responsible must get his/her identification (username and password), in the ECUAPASS website and must have the TOKEN to access the Ecuadorian Single Window (VUE).
2. Access the website of the VUE and submit the application and other requirements for obtaining the health registration of drugs.
3. Application review.
4. Rectification of the application.
5. Electronic payment.
6. Printing / Deplay of the Health Registry Certificate.

More information:
http://www.controlsanitario.gob.ec/inscripcion-de-registro-sanitario-de-medicamentos-fabricacion-nacional/

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL ESTABLISHMENTS

DESCRIPCIÓN:

Through documentary analysis, it is verified that the establishments comply with the basic principles and general hygienic practices in handling, preparation, processing, packaging and storage of products intended for human use and consumption, which ensures that products are manufactured under suitable sanitary conditions.

REQUIREMENTS:

- Request submitted to the Executive Director of the National Agency for Regulation, Control and Health Surveillance (ARCSA - acronym in Spanish) signed by the legal representative and pharmaceutical chemical responsible technician, in the format established for the purpose.

PROCEDURE:

1. Present the request at ARCSA.
2. ARCSA will assign a technical inspection commission for the verification of the compliance under the provisions of the Good Manufacturing Practices Verification Guide.

More information:
http://www.controlsanitario.gob.ec/certificado-de-buenas-practicas-para-establecimientos-farmaceuticos/

OPERATING PERMITS ISSUANCE

DESCRIPTION:

Through the entry of an application and scan requirements, and supported by the applicant in the automated system, the ARCSA www.arcsa.gob.ec issues an enabling document for the operation of the establishments subject to control and health surveillance.

REQUIREMENTS:

1. Request to obtain the operating permit.

PROCEDURE:

1. User login into the computer system of ARCSA (www.arcsa.gob.ec.)
2. Presentation of the request and requirements for the operating permit.
3. The Pharmaceutical Laboratories that have the Good Manufacturing Practices Certificate will obtain the Operating Permit only submitting the request through the computer system of ARCSA.

More information:
http://www.controlsanitario.gob.ec/emision-de-permisos-de-funcionamiento/