

Marketing Authorization Requirements for Chemically Synthesized Drugs in Colombia



Legal and Technical Requirements for Imported products

Legal Requirements

- Power of attorney in favor of SPI – apostilled/legalized.
- Free Sales Certificate (FSC) / CFG / CPP issued by the health authority of the country of origin, confirming that the product is authorized for use in the exporting country (as applicable) – apostilled/legalized/official translation into Spanish.
- GMP Certificate issued directly by INVIMA or by a reference-country authority*. Apostilled/legalized/translated (covering manufacturer, packager, or conditioner, as applicable).
- Letter of Authorization to the importer (LOA) and marketing authorization holder (as applicable).
- Trademark registration.
- IUM application (Unique Drug Identifier).
- Business license and authorized representation for all parties involved (manufacturer, packager, conditioner, importer, and others).

*Accepted GMP authorities: USA, Canada, Germany, Switzerland, France, United Kingdom, Denmark, Netherlands, Sweden, Japan, Norway, Australia, South Korea; and those issued by the FDA, WHO, PAHO, and EMA.

Technical Requirements

- Inclusion in the Pharmacological Standards list. If not listed, a parallel pharmacological evaluation must be submitted.
- Summary of pharmacological information.
- Pharmaceutical form and presentation.
- Qualitative-quantitative composition or formula of the product.
- Structural and condensed formula of the active ingredients.
- Standardized manufacturing batch formula.
- Quality specifications for raw materials.
- In-process product specifications.
- Finished product specifications.
- Analytical methodology for the finished product.
- Validation of the analytical method.
- Stability studies (Climate Zone IVb).
- Artwork for primary and secondary packaging materials, PIL, and prescribing information.
- Bioavailability and bioequivalence studies (if applicable).



*These are general requirements. As the process advances, detailed requirements will be provided based on the specific product type and regulatory classification.



Considerations

- **Legal documents:** Must be legalized in the country of origin and accompanied by an official translation in the destination country.
- **Technical documents:** In Colombia, technical documents may be submitted in English.
- **Marketing authorization holder:** In Colombia, foreign companies may hold sanitary registrations directly.