Sanitary Registration Requirements – Veterinary Products

Requirements	Drugs	Foods	Hygienic Products
Power of attorney of the manufacturer or holder granted in favor of the registrant authorizing him to carry out these activities before the competent authority and legalized and apostilled	x	x	x
Certificate of Free Sale legalized and apostilled	x	x	x
Guaranteed analysis, in original signed and sealed by the technician responsible for the processing or analysis laboratory, expressed in SI units	N.A.	x	N.A.
List of ingredients, comprising the raw materials used, in the formulation with generic or common names, including additives, medicines and vehicles, in original signed and sealed by the technical manager of the manufacturer.	N.A.	x	N.A.
Complete qualitative-quantitative formula, issued by the technician responsible for the producer, including the name of the product	x	x	x
Method of physical, chemical and biological analysis, as appropriate, internationally recognized or validated by the producer, for quality control.	x	x	x
Methodology of physical, chemical and biological analysis, as appropriate, in the case of methods validated by the manufacturer	x	x	N.A.
Process of elaboration of the product, including flowchart (with temperatures, times, pressure and others), in original signed and sealed by the technical manager of the processing establishment.	x	x	N.A.
Certificate of analysis of a commercial batch of the product to be registered, issued by the producer or by the quality control laboratory, in original signed and sealed by the technician responsible for it.	x	x	x
Draft label to be approved by the Competent Authority.	x	x	x
Declaration of shelf life by the manufacturer, specifying under which storage conditions the product remains stable for a certain period of time, expressed in days, weeks, months or years	N.A.	x	N.A.
Analytical standard for medicated foods, as required by the Competent Authority	N.A.	x	N.A.
Where the product used in animal nutrition is manufactured by a company other than the holder of the register, it must produce a legal document or contract between the parties (manufacturing contract).	x	x	N.A.
A sample not exceeding 10 kg in accordance with the analyses to be carried out, sealed by the manufacturer of the product to be registered, accompanied by an original packaging, with which it is intended to be marketed, when required by the Competent Authority	N.A.	x	N.A.
Specifications and Methods of Control of Formula Components (Raw Materials)	x	N.A.	N.A.
Specifications and Methods of Control of the Finished Product	x	N.A.	N.A.
Packaging Specification and Control	x	N.A.	N.A.
Stability Study	x	N.A.	N.A.
Scientific studies or recognized scientific literature, supporting efficacy, stability, safety and quality, for each of the requested species of the product to be registered	x	N.A.	N.A.
A sample of the product to be registered, in the original packaging with which it is marketed in the country of origin, when required by the competent authority	x	N.A.	N.A.
Analytical standard (primary or secondary), as required by the competent authority	x	N.A.	N.A.
Pharmacological Monograph (Indications, dosage, pharmacokinetics, pharmacodynamics, possible side effects (local or general), incompatibilities and pharmacological antagonisms, Intoxication and Overdose in Animals, Intoxication in Man, Unwanted Biological Effects, Controls on Drug Residues , General Precautions	x	N.A.	N.A.

*N.A. = Not Applicable
*All documentation must be submitted in Spanish

For more information please contact: Alejandra López
alopez@vitamas.com.gt
phone:(502) - 24221300 ext 1152