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DEPARTMENT OF AGRICULTURE
Administrative Order No. ___
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DEPARTMENT OF HEALTH
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SUBJECT: REGULATIONS FOR THE LICENSING OF VETERINARY DRUG AND PRODUCT ESTABLISHMENTS AND OUTLETS.

Pursuant to R.A. No. 3720, as amended by Executive Order No. 175 otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", R.A. No. 6675, otherwise known as the "Generics Act of 1988", R.A. 1556, otherwise known as the "Livestock and Poultry Health Act", R.A. 1071, an act to regulate the sale of veterinary biologics and medicinal preparation and R.A. 3701, an Act authorizing the Director of the Bureau of Animal Industry, subject to the approval of the Secretary of Agriculture and Natural Resources to promulgated regulations for the preparation, sale, traffic in shipment and importation of viruses, sera, toxins or analogous products used for the treatment of domestic animals, the following requirements for the licensing of veterinary drug and product establishments and outlets are hereby promulgated for the information, guidance and compliance of all concerned.

In accordance with the above laws, any organization company or business establishments in the veterinary drugs and products industry shall fall under the following general classification:

I. Veterinary Drug and Product Establishment refers to any organization or company involved in the manufacture, importation, repacking, labelling, advertising and/or distribution of veterinary drugs and products. This is covered by Chapter I below.

II. Veterinary Drug Outlet refers to drugstore, pharmacy, livestock and poultry supply store and other business establishments selling veterinary drugs and products. This is covered by Chapter II below.

CHAPTER I – VETERINARY DRUG AND PRODUCT ESTABLISHMENTS

Definition of Different Types of Veterinary Drug and Product Establishments

.1 Veterinary Drug and Product Manufacturer refers to any establishment engaged in operations involved in the production of a drug including propagation, processing, compounding, finishing, filling, repacking, labelling, advertising, storage distribution or sale of the veterinary drug product: provided that for the purpose of this regulation the compounding and filling of prescription by drugstores shall not be considered as production operations.

.2 Veterinary Drug and Product Trader refers to any establishment which is a registered owner of the drug product, procures the raw materials and packaging components, and provides the production monographs, quality control standards and procedures, but sub-contracts the manufacture of such veterinary drug and product to a licensed manufacturer. In addition, a trader may also engage in distribution, and/or marketing of its veterinary drugs and products.

.3 Veterinary Drug and Product Distributor/Importer refers to any veterinary drug and product establishment that imports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other drug establishments or outlets.

.4 Veterinary Drug and Product Distributor/Exporter refers to any veterinary drug and product establishment that exports raw materials, active ingredients and/or finished products to another country.

.5 Veterinary Drug and Product Distributor/Wholesaler refers to any veterinary drug and product establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

tandards and Requirements for License to Operate (LTO)

.1 General Requirements

2.1.1 Application - any person desiring to operate or establish a veterinary drug and product establishment shall file with the BFAD/BAI an application supported by the following documents:

2.1.1.1 A standard petition form containing among others the name, age, citizenship

and a passpo size picture (5 x 5 cm) of the petitioner and other pertinent circumstances pertaining to the proposed veterinary drug and product establishment including the place where it is to be established.

2.1.1.2 Proof of registration as an establishment, i.e.:

a) For single proprietorship; an authenticated photocopy of the certificate of Business Name Registration issued by the Bureau of Domestic Trade (BDT) of the Department of Trade and Industry.

b) For partnerships, corporations and other juridical persons authenticated photocopies of the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and the Articles of Incorporation or Partnership.

2.1.1.3 A valid Certificate of Registration of the establishment's Filipino Veterinarian issued by the Professional Regulation Commission (PRC).

2.1.1.4 A valid Certificate of Registration of the establishment's Filipino Pharmacist issued by the Professional Regulation Commission (PRC).

2.1.1.5 A valid credential of the establishment's Filipino Microbiologist in case of veterinary biological manufacturer and trader.

2.1.1.6 A certificate of attendance to a BFAD/BAI sponsored/accredited Seminar on Licensing of Veterinary Drug and Product Establishments:

2.1.1.7 An Affidavit of Undertaking providing that the applicant shall;

a) change the establishment's name if there is already a validly registered name similar to it.

b) display the duly approved LTO in a conspicuous place within the establishment.

c) otify BFAD/BAI in case of any hange in the circumstances escribed in the application, among others; change of location, change of veterinarian, change of pharmacist, change in veterinary drugs and products.

2.1.1.8 An authenticated photocopy of Contract of Lease for the space to be occupied if the applicant does not own it.

2.1.2 A Certificate of continuing compliance with specific technical requirements (to be specified by BFAD/BAI according to section 2.2 below).

2.1.3 A Batch Distribution Record Book duly registered with BFAD/BAI.

2.1.4 A contingency plan or procedure for a systematic, effective and prompt recall in case any of its products is found violative and ordered recalled from the market by BFAD/BAI.

2.1.5 An orderly and secure system of filing up to date invoices from suppliers and buyers identifying lot numbers or batch numbers of manufacturers stock pursuant to BFAD Memo Circular No. 001 s. 1983.

Specific Requirements:

An entity applying for a LTO as a veterinary drug and product manufacturer or veterinary drug and product trader or veterinary drug and product distributor shall be required to demonstrate its capacity to perform adequately as such in a manner that satisfactorily assumes the safety, efficacy and quality of its veterinary drugs and products. It shall be required to conform with the following relevant standards and requirements specific for each category, in addition to the above general requirements.

2.2.1 Veterinary Drug Manufacturers

2.2.1.1 Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD.

2.2.1.2 Minimum standards for pharmaceutical manufacturing equipment/machines owned by the manufacturers described in Annex A;

2.2.1.3 Minimum standards for quality control facilities owned by the manufacturers described in Annex B.

2.2.1.4 For importing raw materials, active ingredients and/or finished products for use in manufacture of veterinary drug and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment. However, in lieu of the above a Certification Scheme from WHO or from an acceptable equivalent drug regulatory agency or organization.

2.2.2 Veterinary Biological Manufacturers

2.2.2.1 Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD, administrative Order No. 9 issued by BAI and other guideline as required by NDC and other agencies.

2.2.2.2 Minimum standards for veterinary biological manufacturing equipment/ machine described in Annex C.

2.2.2.3 Minimum standards for quality control facilities described in Annex D.

2.2.2.4 If importing raw materials, active ingredients and/or finished products for use in manufacture of veterinary drug and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.3 Veter ary Medicat d Feeds, Medicated Feed Premi Medicated Feed Supplement, Medicated Feed dditive and Medicated Water Additive Manu turer

Medicated feed refers to any feed which contains drug ingredients intended or represented for the cure, mitigation, treatment or prevention of diseases of animal other than man or which contains drug ingredients intended to affect the structure or any function of the body of animal other than man.

2.2.3.1 Relevant Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD and Administrative Order No. 35 issued by BAI.

2.2.3.2 Minimum standards for Veterinary Medicated Feed Manufacturing equipment/ machines described in Annex E.

2.2.3.3 Minimum standards for quality control facilities described in Annex F whether owned or contracted by the manufacturer provided the contracted quality control facility is accredited by BAI.

2.2.3.4 If importing raw materials, active ingredients and/or finished products for use in manufacture of veterinary drugs and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate any equivalent government regulatory agency and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.4 Veterinary Drug and Product Traders

2.2.4.1 A valid contract of agreement with a BFAD/BAI Licensed manufacturer containing a stipulation that both

the veterinary drug trader and the manufacturer are jointly responsible for the quality of the veterinary drug and product;

2.2.4.2 If importing raw materials, active ingredients and/or finished products for use in the manufacture of veterinary drug and product, a certificate that the manufacturer is registered with the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by the BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment;

2.2.4.3 A description of the production process and quality control procedures to be followed by the contracted manufacturer, jointly certified by the owner and the pharmacist of the veterinary drug and product establishment.

2.2.5 Veterinary Drug and Product Distributors

2.2.5.1 Importers

2.2.5.1.1 Foreign Agency Agreement between the Philippine importer and foreign supplier duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency.

2.2.5.1.2 A certificate that the manufacturer of the raw material, active ingredient and/or finished product is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency and evidence that

the manufacturer meets BFAD/ BAI standards for local manufacturers. If inspection of the foreign manufacturers of the BFAD/BAI in needed the cost of inspection shall be borne by the applicant establishment.

2.2.5.1.3 In case of finished products, Certificate of Free Sale of the product in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency and evidence that such certificate is issued in substantial compliance with BFAD/BAI standards.

2.2.5.2 Exporters

2.2.5.2.1 A valid contract with BFAD/ BAI licensed manufacturer in addition to other requirements set by other competent authorities.

2.2.5.3 Wholesalers

2.2.5.3.1 A valid contract with a BFAD/ BAI licensed veterinary drug and product manufacturer, trader or distributor.

2.2.5.3.2 A certification that the products it sells are registered with BFAD/BAI.

2.3 Other Additional Requirements:

In addition to the above standards and requirements, BFAD/BAI in the course of evaluating an application may require other additional documentation or evidence to satisfactorily ascertain the capability of the veterinary drug and product establishment.

Renewal of License To Operate (LTO)

3.1 The License to Operate shall have the following validities for all categories of veterinary drug and product establishments:

3.1.1 Initial Period (Initial Application) 1 year

3.1.2 Subsequent Period (Renewal Application) 2 years

3.2 At least one month prior to the expiration of the LTO, veterinary drug and product establishments shall apply to renew their license.

3.3 In considering the renewal application, BFAD/BAI shall ascertain the continued compliance by the veterinary drug and product establishment with the standards and requirements stipulated in section 2.1 and 2.2.

Administrative Sanctions

4.1 Grounds for Revocation of LTO

4.1.1 Misrepresentation of any material fact in the application for LTO and in any documentation used as a basis for issuing the LTO.

4.1.2 For manufacturers and traders: any deficiency in GMP that is likely to result in adulterated, misbranded, substandard or unsafe products as determined by BFAD/BAI. This includes, among others, grossly inadequate premises, lack of key technical and professional personnel, lack of key equipment in production or quality control, poor or inadequate process control and inadequate or improper documentation of the production process.

4.1.3 For distributors: distribution of fake, substandard, misbranded, adulterated or unsafe veterinary drugs and products.

4.1.4 Violation of BFAD/BAI standards of quality, efficacy, purity and safety of veterinary drugs and products.

4.1.5 Sale and distribution of therapeutic antibiotic and biological products without batch certification by BFAD/BAI.

4.1.6 Failure to take adequate remedial or corrective measures for deficiencies identified in accordance with requirements of BFAD/BAI.

4.1.7 Failure to keep up to date, secure, orderly, and easily inspected records that would indicate continued compliance with standards.

4.2 Grounds for Suspension of LTO

4.2.1 Minor deficiencies in GMP or material management that need to be corrected but are not immediately or likely to result in adulterated, misbranded, substandard, or unsafe veterinary drugs and products as determined by BFAD/BAI. These include, among others, poor housekeeping, inadequate storage facilities, non-functional equipment, and failure to comply with laboratory safety standards.

4.2.2 Lapses in record keeping of invoices, receipts or distribution records.

4.3 Re-application After Revocation

No establishment whose LTO was revoked may apply for an LTO within 5 years after the revocation of its license.

Schedule of Fees

5.1 Upon application for a license to operate as a veterinary drug and product establishment, the following non-refundable fees shall be charged for each application:

Veterinary Drug and Product Manufacturer (Code VDAPM)
Veterinary Drug and Product Trader (Code VDAPT)
Veterinary Drug and Product Distributor (Code VDAPDW/ VDAPDE/VDAPDI)

Code	Initial	Renewal (good for 2 years)
VDAPM	P 5,000	P 10,000
VDAPT	3,000	6,000
VDAPDW/VAPDE/VPAPDI	2,000	4,000

5.2 If a veterinary drug and product establishment engages in activities belonging to more than one of the above categories, applicant must apply for LTO for each of the category and pay the corresponding fees.

5.3 Only upon payment of application fees may the application be processed. A surcharge of fifty percent (50%) of the above fees shall be imposed on applications for renewal filed after the validity of the license has lapsed. Any change in the category of veterinary drug and product establishment or change in ownership shall require a new application.

CHAPTER II - VETERINARY DRUG AND PRODUCT OUTLETS

Definitions of Different Types of Veterinary Drug and Product Outlets

1.1 Drugstore, Pharmacy and Botica are drug outlets where registered veterinary drugs and products, chemical products, active principles, proprietary medicines or pharmaceutical specialties are compounded and/or dispensed and sold, excluding veterinary Hospitals, Clinic and Farm storage areas where drugs and products are stored for their exclusive use.

1.2 Veterinary and agricultural supply store, livestock and poultry supply store and any other outlet selling prescription veterinary drugs and products.

1.3 Retail outlet for non-prescription drugs including non-traditional outlets such as supermarkets and stores, means a drug outlet where registered non-prescription or over-the-counter (OTC) or self-service (SS) Veterinary drugs and products are sold in their original packages, bottle or containers or in smaller quantities not in their original containers.

Standards and Requirements for License to Operate (LTO)

2.1 General Requirements

2.1.1 Application of any person desiring to operate or establish a veterinary drug and product outlet shall file with the BFAD/BAI application supported by the following documents:

2.1.1.1 A standard petition form containing among others the name, age, citizenship and a passport size picture (5X5cm) of the petitioner and other pertinent circumstances pertaining to the proposed veterinary drug and product outlet including the place where it is to be established.

2.1.1.2 Proof of registration as an establishment, i.e.:

a) For single proprietorship: an authenticated photocopy of the Certificate of Business Name Registration issued by the Bureau of Domestic Trade (BDT) of the Department of Trade and Industry.

b) For partnership, corporation and other juridical persons; authenticated photocopies of the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and the Articles of Incorporation or partnership.

2.1.1.3 A valid Certificate of Registration of the establishment's Filipino Pharmacist/Veterinarian issued by the Professional Regulation Commission (PRC).

2.1.1.4 A certificate of attendance to a BFAD/BAI accredited Seminar for Licensing of veterinary drug and product outlet.

2.1.1.5 An Affidavit of undertaking providing that the applicant shall:

a) change the establishment's name if there is already a validly registered name similar to it.

b) display the duly approved LTO in a conspicuous place within the establishment.

c) notify BFAD/BAI in case of any change in the circumstances described in the application such as: change of location, change of pharmacist etc.

2.1.1.6 Tentative list of veterinary drugs and products intended to be sold using generic names with brand names when applicable.

2.1.1.7 An authenticated photocopy of Contract of Lease for the space to be occupied if the applicant does not own it.

2.1.2 For drugstore, pharmacy or botiça, see Specific Requirements 2.2.1.

2.2 Specific Requirements:

Any entity applying for a license to operate drugstore, pharmacy or botica or retail outlet shall be required to demonstrate its capacity to perform adequately its functions to inform its clientele in accordance with Section 8 (d) of R.A. 6675 and sell veterinary drugs and products, which are safe, effective, and of good

quality to the public. It shall be required to conform with relevant standards and requirements specific for each category, in addition to the foregoing general requirements.

2.2.1 Drugstore, Pharmacy or Botica requirements are provided for in A.O. No. 56 s. 1989 and therefore shall secure the license to operate from the BFAD. However, they shall secure a license to operate from the BAI if they shall sell veterinary drugs and products. Such LTO shall be automatically granted by the BAI upon presentation of LTO from BFAD, payment of corresponding fees and tentative list of veterinary drugs and products intended to be sold using generic names with brand names when applicable.

2.2.2 Veterinary and agricultural supply store, livestock and poultry supply store are outlets selling prescription veterinary drugs and products.

2.2.2.1 Premises

2.2.2.1.1 A signboard in front of the place of business bearing the registered name of the veterinary drugstore. For veterinary drug and product outlet selling exclusively non-prescription or over the Counter (OTC) or self service veterinary drug and product, the signboard should indicate so by putting the symbol non-Rx or equivalent.

2.2.2.1.2 A well-ventilated area not less than 12 sq.m. in floor are with concrete, tile or wooden flooring.

2.2.2.1.3 A suitable and proper place (e. g. refrigerator) for the adequate storage of veterinary drugs and products as specified on the label.

2.2.2.1.4 A suitable cabinet for keeping poisons and/or dangerous drugs, when applicable.

2.2.2.1.5 An adequate water and electrical supply.

2.2.2.1.6 Other additional requirements of BAI and FPA.

2.2.2.2 Reference Books and Documents

2.2.2.2.1 Philippine National Veterinary Drug Formulary.

2.2.2.2.2 Philippine Veterinary Drug Codex

2.2.2.2.3 R.A. 3720, otherwise known as the Foods, Drugs and Devices and Cosmetics Act as amended and relevant implementing rules and regulations.

2.2.2.2.4 R.A. 6675, Generics Act of 1988 and relevant implementing rules and regulations.

2.2.2.2.5 R.A. 5921 Pharmacy Law, as amended and relevant implementing rules and regulations.

2.2.2.2.6 R.A. 3101, An Act authorizing the Director of Animal Industry to promulgate regulation for the preparation, sale, traffic in, and shipment, and importation of viruses, serum, toxins, or analogue products used for the treatment of domestic animals and relevant implementing guidelines.

2.2.2.2.7 R.A. 1071, An Act to regulate the sale of veterinary biologics and medicinal preparation and relevant implementing guidelines.

2.2.2.2.8 R.A. 1556 Livestock and Poultry Feeds Act and relevant implementing guidelines.

2.2.2.3 Record Books Duly Registered with the RFAD/BAI.

2.2.2.3.1 Prescription Book

2.2.2.3.2 Dangerous Drug Book, when applicable

2.2.2.3.3 Poisons Book, when applicable

2.2.2.4 A duly BFAD/BAI registered pharmacist or veterinarian.

2.2.2.5 Other Additional Requirements:

2.2.2.5.1 Invoices indicating the lot number or batch number of the manufacturer's stock pursuant to BFAD Memo. Circulr No. 001 s. 1983.

2.2.2.5.2 File of prescriptions filled, consecutively numbered.

2.2.2.5.3 Dry Seal or Rubber Stamp containing the name and address of the veterinary drug and product outlet.

2.2.3 Requirements for a Retail Outlet for Non-Prescription, Over the Counter and Self-Service Veterinary Drugs and Products.

2.2.3.1 Premises

2.2.3.1.1 A signboard in front of the place of business bearing the registered name of retail outlet and the symbol non-Rx or equivalent.

2.2.3.1.2 An adequate, well ventilated area with concrete, tile, or wooden flooring.

2.2.3.1.3 A suitable and proper place for the adequate storage of non-prescription drugs. When there are products sold other than drugs, area exclusively for veterinary drugs and products shall be allocated within the premises.

2.2.3.2 Reference Books and Documents

2.2.3.2.1 Philippine National Veterinary Drug Formulary

2.2.3.2.2 Philippine Veterinary Drug Index

2.2.3.2.3 R.A. 5921, Pharmacy Law and its implementing rules and regulations;

2.2.3.2.4 R.A. 6675 the Generics Act of 1988 and relevant implementing rules and regulations;

2.2.3.2.5 R.A. 3720 as amended or Foods, Drugs and Devices and Cosmetics Act;

2.2.3.2.6 R.A. 3101,An Act authorizing the Director of Animal Industry to promulgate regulation for the preparation, sale, traffic in and shipment, and importation of viruses, serum, toxins, or analogue products used for the treatment of domestic animals and relevant implementing guidelines.

2.2.3.2.7 R.A. 1071, An Act to regulate the sale of veterinary biologics and medicinal preparation and relevant implementing guidelines.

2.2.3.2.8 R.A. 1556 Livestock and Poultry Feeds Act and relevant implementing guidelines

2.2.3.3 Other Additional Requirements

2.2.3.3.1 Invoice indicating the lot number or batch number of the manufacturer's stock pursuant to BFAD Memo. Circular No. 001 s. 1983.

2.2.3.3.2 Dry Seal or Rubber Stamp containing the name and address of the veterinary drug and product outlet.

Renewal of License to Operate (LTO)

In case of renewal of LTO the Veterinary drug and product outlet must have a history of satisfactory

performance, consistent with BFAD/BAI standards and requirements, without any cases of serious violation of existing laws, rules and regulations.

Administrative Sanctions

4.1 Temporary Closure

Failure to comply with the standards and requirements for LTO as cited above.

4.2 Suspension of License to Operate

4.2.1 Failure to produce invoices and receipts together with lot number, expiry dates for the veterinary drugs and products in stock.

4.2.2 Failure to properly record and keep a file of all prescriptions filled in the last two years.

4.2.3 Refusal to allow entry of BFAD/BAI inspectors.

4.3 Revocation of License to Operate

4.3.1 Sale or Offer for sale of adulterated, misbranded, sub-standard, unregistered, expired and/or unsafe veterinary drugs and products marked "Not for Sale".

4.3.2 Failure to properly record dangerous drugs as determined by DDB.

4.3.3 Lack of pharmacist/veterinarian.

4.3.4 Failure to take necessary remedial or corrective measures within the prescribed period as directed by BFAD/BAI.

Validity

The license to operate shall have the following validities:

Initial Period of validity	Validity of Subsequent Renewal
1 year	2 years

Schedule of Fees

Upon application for a license to operate, the following non-refundable fees shall be charged for each application:

Initial	Renewal (go 3 for two years)
P 200.00	P 100.00

Only upon payment of application fees may the application be processed. A surcharge of fifty percent (50%) of the above fees shall be imposed on applications for renewal filed after the validity of the license has lapsed.

SEPARABILITY CLAUSE

In case any provision of this rules and regulations is declared contrary to law or unconstitutional other provisions which are not affected thereby shall continue to be in force and in effect.

REPEALING CLAUSE

All administrative orders, rules and regulations and other administrative issuances or parts thereof, inconsistent with the provisions of this Regulation are hereby repealed or modified accordingly.

EFFECTIVITY

This Regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

SENEN C. BACANI
Secretary of Agriculture

ALFREDO R.A. BENGZON, M.D.
Secretary of Health

Initial	Renewal (good for two years)
P 200.00	P 400.00

Only upon payment of application fees may the application be processed. A surcharge of fifty percent (50%) of the above fees shall be imposed on applications for renewal filed after the validity of the license has lapsed.

SEPARABILITY CLAUSE

In case any provision of this rules and regulations is declared contrary to law or unconstitutional other provisions which are not affected thereby shall continue to be in force and in effect.

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Secretary of Health

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ANNEX A

MINIMUM STANDARDS FOR PHARMACEUTICAL MANUFACTURING EQUIPMENT/MACHINES

0 General Machinery and Equipment

1.1 Weighing scale

1.1.1 1 g. sensitivity
1.1.2 1 kg. sensitivity

1.2 Labelling device
1.3 Coding device
1.4 Facility for washing and drying bottles
1.5 Measuring glasswares
Laboratory apparatus including measuring glasswares, chemical supplies, filter paper.

.0 Additional Machine and Equipment needed for each dosage form:

2.1 Liquid/Suspension

2.1.1 Stainless Steel tank with stirrer of appropriate capacity.
2.1.2 Jacketed Kettle
2.1.3 Homogenizer
2.1.4 Stainless steel pail, assorted sizes
2.1.5 Deionizer or distilling apparatus
2.1.6 Stainless steel storage tank 500 L
2.1.7 Filter Assembly
2.1.8 Filling Machine
2.1.9 Pilfer-proof capper

2.2 Tablet

2.2.1 Mixer/blender
2.2.2 Mill
2.2.3 Granulator
2.2.4 Drying Oven or fluidized-bed dryer
2.2.5 Sifter/Sieve
2.2.6 Tablet Press
2.2.7 Dust collector/exhaust system
2.2.8 Dehumidifier

2.3 Capsule

2.3.1 Mixer
2.3.2 Dehumidifier
2.3.3 Encapsulating machine
2.3.4 Dust collector/exhaust system

2.4 Powder/Granule Preparation

2.4.1 Blender

2.4.2 Powder filling machine
2.4.3 Tamper-proof machine
2.4.4 Dehumidifier

2.5 Sterile products (Ophthalmic, etc.)

2.5.1 Stainless steel tank with stirrer
2.5.2 Stainless steel storage tank
2.5.3 Membrane filter assembly
2.5.4 Laminar flow system
2.5.5 Filling machine
2.5.6 Capping machine

2.6 Ointment/Cream

2.6.1 Mill
2.6.2 Stainless tank with stirrer, jacketed
2.6.3 Filling machine
2.6.4 Crimper

2.7 Small Volume Parenteral Products

2.7.1 Vial washer/rinser
2.7.2 Pyrogen-free distilling apparatus
2.7.3 Storage tank s.s.
2.7.4 Stainless steel tank with stirrer
2.7.5 Membrane filter assembly
2.7.6 Laminar flow system
2.7.7 Ampule filler and sealer
2.7.8 Vial filler and sealer/crimper
2.7.9 Filling machine for liquid
2.7.10 Sterilizer/autoclave
2.7.11 Depyrogenating oven

2.8 Large Volume Parenteral Products

2.8.1 Water softener
2.8.2 Carbon filter
2.8.3 Deionizer
2.8.4 Distilling unit
2.8.5 Stainless steel tank with stirrer
2.8.6 Stainless steel storage tank
2.8.7 Membrane filter assembly
2.8.8 Bottle/stopper washer
2.8.9 Laminar flow assembly
2.8.10 Filler and sealer/crimper
2.8.11 Vacuum equipment
2.8.12 Autoclave/sterilizer
2.8.13 Depyrogenating oven

ANNEX B

MINIMUM STANDARDS FOR QUALITY CONTROL FACILITIES (DRUG MANUFACTURERS)

1 GENERAL REQUIREMENTS

1.1 Physico - Chemical Assay

1.1.1 UV spectrophotometer
1.1.2 Fluorophotometer (for Vitamin preparation)
1.1.3 Titrimeter
1.1.4 Thin layer chromatography
1.1.5 Analytical balance
1.1.6 pH meter
1.1.7 Drying oven
1.1.8 Oven for stability testing
1.1.9 Water bath
1.1.10 Magnetic Stirrer
1.1.11 Mechanical shaker
1.1.12 Pycnometer
1.1.13 Desiccators/vacuum desiccators
1.1.14 Hot plate
1.1.15 Furnace
1.1.16 Glasswares

1.1.16.1 Burett (4)
1.1.16.2 Volumetric flask (6)
1.1.16.3 Separatory funnel (3)
1.1.16.4 Erlenmeyer flask (3)
1.1.16.5 Beaker (assorted sizes, 2 pcs. of each size)
1.1.16.6 Graduated cylinder (assorted sizes, 2 pcs. of each size)
1.1.16.7 Pipette (6)
1.1.16.8 Thermometer (2)
1.1.16.9 Test tube (24)
1.1.16.10 Funnel (4)
1.1.16.11 Stirring rod (6)
1.1.16.12 Crucible (6)

1.1.17 Laboratory supplies/chemicals/reagents/reference standards, etc.

1.2 Biological Assay

1.2.1 Micro Assay

1.2.1.1 Autoclave
1.2.1.2 Centrifuge
1.2.1.3 Incubator
1.2.1.4 Refrigerator
1.2.1.5 Bunsen Burner

1.2.1.6 Petri Dishes (24 pieces)
1.2.1.7 Microscope
1.2.1.8 Laboratory supplies/glasswares/chemicals/culture/media etc.

1.2.2 Laboratory Animal Facility in a separate building

1.3 Reference Materials

1.3.1 Latest covered edition United States Pharmacopeia/National Formulary or
1.3.2 British Pharmacopoia latest edition
1.3.3 Remington's Pharmaceutical Sciences
1.3.4 Drug Reference Manual
1.3.5 BFAD/BAI Regulations/Pharmacy Laws/Veterinary Practice Laws
1.3.6 Official Philippine National Veterinary Drug Formulary

1.4 Other Requirements (if applicable)

1.4.1 Coloring
1.4.2 Column chromatography
1.4.3 Gas-liquid chromatography
1.4.4 Infrared spectrophotometer
1.4.5 Polarimeter
1.4.6 Polarography
1.4.7 High pressure liquid chromatography
1.4.8 Ultrasonic bath
1.4.9 Kjeldahl assembly

2.0 Additional Requirements based on dosage form to be manufactured.

2.1 Tablet Preparation

2.1.1 Disintegration tester
2.1.2 Dissolution rate assembly
2.1.3 Friabilator
2.1.4 Hardness tester
2.1.5 Caliper
2.1.6 Moisture balance
2.1.7 Torsion balance/analytical balance
2.1.8 Melting point apparatus

2.2 Capsule Preparation

2.2.1 Dissolution rate assembly
2.2.2 Moisture balance
2.2.3 Melting point apparatus
2.2.4 Torsion balance/analytical balance

3 Liquid/Suspension

2.3.1 Viscosimeter
2.3.2 Refractometer
2.3.3 Visual inspection assembly
2.3.4 pH meter

4 Powder and Granules

2.4.1 Visual inspection system
2.4.2 Torsion balance/analytical balance
2.4.3 Sec. 2.3 Requirements for liquid/suspension

5 Parenteral

2.5.1 Visual inspection system
2.5.2 Leaker test (Set-up) for ampules
2.5.3 Pyrogen test set-up
2.5.4 Particle counter

6 Ointment/Cream

2.6.1 Viscosimeter
2.6.2 pH meter

7 Penicillin Preparation

2.7.1 Separate equipment from that of non-penicillin products depending on the dosage form to be manufactured

ANNEX C

INIMUM STANDARDS FOR BIOLOGICAL MANUFACTURING EQUIPMENT/MACHINE

General Machinery and Equipment

1.1 Analytical balance
1.2 Labelling machine
1.3 Facility for washing and drying bottles
1.4 Facility for sterilising bottles and glasswares
1.5 Incinerator
1.6 Cold storage

Bacterial Vaccine Production

2.1 Pyrogen free distilling apparatus
2.2 Laminar flow system
2.3 Autoclave/sterilizer
2.4 Microscope
2.5 Biological Incubator
2.6 Fermentor
2.7 Roux bottles
2.8 Crimping machine
2.9 pH meter
2.10 Spectrophotometer
2.11 Water bath
2.12 Drying oven
2.13 Filling machine

Viral Vaccine Production

3.1 Laminar flow system
3.2 Tissue culture microscope
3.3 Roux bottles
3.4 pH Meter
3.5 Autoclave/Sterilizer
3.6 Centrifuge
3.7 Freeze dryer
3.8 Filter system
3.9 Magnetic stirrer
3.10 Refrigerated centrifuge
3.11 Water bath
3.12 Vacuum pump
3.13 Deep freezer
3.14 Refrigerator
3.15 CO2 incubator
3.16 Crimping machine
3.17 Filling machine
3.18 Egg incubator

ANNEX D

MINIMUM STANDARDS FOR QUALITY CONTROL FACILITIES (VETERINARY BIOLOGICAL MANUFACTURER)

1. General Requirements

1.1 Laminar flow system
1.2 Egg incubator (Viral vaccine)
1.3 Incubator
1.4 Centrifuge
1.5 Laboratory animal facility (separate area)
1.6 Refrigerator
1.7 Microtiter system
1.8 Light microscope
1.9 F.A. microscope
1.10 Tissue culture microscope

2. Additional Requirements

2.1 Reference Materials

2.1.1 Philippine National Veterinary Drug Formulary
2.1.2 Essential of Veterinary Bacteriology and Mycology, Carter 1986
2.1.3 Appropriate BAI Rules and Regulations
2.1.4 Generics Law and its Implementing Guidelines
2.1.5 General Virology
2.1.6 Veterinary Immunology Tizard, 1987
2.1.7 ASEAN Standards for Veterinary Biological Products

ANNEX E

MINIMUM STANDARDS FOR MEDICATED FEED MANUFACTURING EQUIPMENT/MACHINES

1. Weighing scale

   1.1 1g sensitivity
   1.2 1 kg sensitivity
   1.3 100 kg sensitivity

2. Labelling device

3. Coding device

4. Mixer/blender

5. Bag closer/sealer

6. Facility for washing and drying bottles

7. Mill

8. Sifter/sievor

9. Dust collector/exhaust system

10. Dehumidifier for powder preparation

ANNEX F

MINIMUM STANDARDS FOR QUALITY CONTROL FACILITIES (MEDICATED FEED MANUFACTURERS)

1.0 General Requirements

1.1 Physico - Chemical Assay

1.1.1 UV spectrophotometer
1.1.2 Fluorophotometer (for Vitamin preparation)
1.1.3 Titrimeter
1.1.4 Thin layer chromatography
1.1.5 Analytical balance
1.1.6 pH meter
1.1.7 Drying oven
1.1.8 Oven for stability testing
1.1.9 Water bath
1.1.10 Magnetic stirrer
1.1.11 Mechanical shaker
1.1.12 Pycnometer
1.1.13 Desiccators/vacuum desiccators
1.1.14 Hot plate
1.1.15 Furnace
1.1.16 Glasswares

1.1.16.1 Burett (4)
1.1.16.2 Volumetric flask (6)
1.1.16.3 Separatory funnel (3)
1.1.16.4 Erlenmeyer flask (3)
1.1.16.5 Beaker (assorted sizes, 2 pcs. of each size)
1.1.16.7 Pipette (6)
1.1.16.8 Thermometer (2)
1.1.16.9 Test tube (24)
1.1.16.10 Funnel (4)
1.1.16.11 Stirring rod (6)
1.1.16.12 Crucible (6)

1.1.17 Laboratory supplies/chemicals/reagents/reference standards, etc.

1.2 Biological Assay

1.2.1 Micro Assay

1.2.1.1 Autoclave
1.2.1.2 Centrifuge
1.2.1.4 Incubator
1.2.1.5 Refrigerator
1.2.1.6 Bunsen Burner
1.2.1.7 Petri Dishes (24 pieces)
1.2.1.8 Microscope
1.2.1.9 Laboratory supplies/glasswares/ chemicals/culture/media etc.

1.2.2 Animal House and Laboratory Animals

i.e. mice for safety test; rabbits for pyrogen test

1.3 Reference Books

1.3.1 Latest United States Pharmacopeia/National Formulary
1.3.2 British Pharmacopeia latest edition
1.3.3 Remington's Pharmaceutical Sciences
1.3.4 Merck Index
1.3.5 Drug Reference Manual
1.3.6 BFAD/BAI Regulations/Pharmacy Laws
1.3.7 Official Philippine National Veterinary Drug Formulary
1.3.8 Association of Official Analytical Chemists

1.4 Optional Requirements

Note: If product to be manufactured requires the use of any of the following then it becomes mandatory.

1.4.1 Coloring
1.4.2 Column Chromatography
1.4.3 Gas-liquid chromatography
1.4.4 Infrared spectrophotometer
1.4.5 Polarimeter
1.4.6 Polarography
1.4.7 High pressure liquid chromatography
1.4.8 Ultrasonic bath
1.4.9 Kjeldahl assembly

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