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THE DRUGS PRODUCTION CODE, 2041 (1984)

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Whereas, for purposes of Rule 11 of the Drugs Registration Regulation, 2038 (1981), the Government of Nepal has enforced the Drugs Production Code as follows;

Now, therefore, this notice is hereby published for information of the general public.

1. Short title and commencement:

(1) This Code may be cited as the "Drugs Production Code, 2041(----)."

(2) This Code shall come into force at once.

2. Definitions:

Unless the subject or the context otherwise requires, in this Code,

"person" means a person who establishes a drug industry and who produces drugs pursuant to the Drugs Act, 2035(1978) and the Drugs Registration Regulation, 2038 (1981).

3. Observance of Code:

(1) Each person has to observe the matters contained in this Code.

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(2) If any person performs conduct contrary to the matters contained in this Code, such person shall be considered to have violated this Code.

4. Place where production building is situated:

A building where a drug is produced should not be situated in the following place:

(a) Place where a public toilet or dumping site is not situated, or

(b) Place where foul gas and much smoke come out and where environment is polluted.

5. Arrangements for production of drugs in building:

(1) General arrangements:

There shall be minimum provisions as follows in a building which is used to produce a drug:

(a) Adequate water, fresh air and ventilation,

(b) Necessary electrical power or necessary energy,

(c) Arrangement for emission of polluted air or gas,

(d) Environment where activities can be done in a healthy manner,

(e) Arrangement for disposal, burial, destroy of wastes from production or killing of poisonous substance so that it does not cause injury to public health,

(f) Toilet, adequate water and bathing facility,

(g) Provisions of and arrangements for means protecting accidents from fire,

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(h) Separate room for storing the industrial raw materials so that they are not mixed up, production room and room for storing produced drugs, and

(i) Arrangements for always keeping the production rooms neat and clean.

(2) Special arrangements:

In addition to the matters of general arrangements for the preparation of parental drugs, provisions have to be made so that unrelated persons are not allowed to enter the production building and rooms should be such with provisions to keep it free from dust, biotic or micro-organism in a required amount. Healthy environment has to be maintained in the production room in order to preserve it from other pollution. Such room has to be as follows:

(a) There should be a separate room for the storage, cleaning up of raw materials, making solution and filling, sealing and sterilizing containers, packing, labeling, and for storing prepared drugs. In addition, there should be following provisions:

(1) The ceiling and floor of the clean up room should be of smooth surface so that it can be easily washed and its roof should be water proof,

(2) The room for preparation of liquid should be built so that its floor and ceiling are smooth and easily washable and its roof should be water proof. And it shall be air conditional.

(3) The roof, floor and ceiling of the filling and sealing room should be water proof and built in a manner that the same can be washed with disinfectant liquids. Such

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room should have such air-lock provision that dust or pests cannot enter it and air is allowed through filter and air cannot enter from outside. In addition, this room should be in positive pressure.

(4) (a) The room for filling and sealing drugs without terminal sterilization room should be as mentioned above in clause (3) and also have provision required to strictly control micro-organisms, for example provision of fumigation.

(b) It should be as mentioned in clause (3) above in the case of drugs with terminal sterilization.

(b) Provisions should be made to store raw materials and prepared drugs in such manner that quality thereof is not affected adversely.

6. **Instruments required for production of drugs:**

A person producing drugs should manage the following instruments to be used in production according to the structure of drugs:

(a) For the production of drugs falling within liquid category (elixir, mixture, syrup, lotion, liniment, drop, spray, gyalenicals etc,):

(1) Scale or scales to weigh or measure correctly,

(2) Mixture pots,

(3) Percolator (for gyalenicals)

(4) Boiling container or containers,

(5) Container or containers used to make mixture in a suitable manner,

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(6) Means to make dusts,

(7) Filter machine or means,

(8) Machine to fill drugs in bottles or containers,

(9) Means to inspect whether any other matter such as a foreign particle is mixed with filled drugs,

(10) Machine or means to clean and dry bottles, glasses or containers,

(11) Machine to make deionizer or distill water, and

(12) Measuring instruments.

(b) For the production of ointment and pest:

(1) Scale or scales to weigh or measure correctly,

(2) Mixture pots,

(3) Boiling container or containers,

(4) Container or containers used to make mixture in a suitable manner,

(5) Tanks or containers for storage,

(6) Colloidal mill, triple mill or similar other mills (for drugs of colloidal structure),

(7) Machine to fill ointment in bottles or containers,

(8) Paste filling machine (for paste),

(9) Machine or means to clean bottles or containers, and

(10) Machine to make deionizer or distill water.

(c) For tablets and capsules:

(1) Scale or scales to weigh or measure correctly,

(2) Disintegrator or dust machine,

(3) Powder mixture,

(4) Mass mixture,

(5) Granulator,

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(6) Oven or drier with heating control system,

(7) Tablet making machine (for tablets),

(8) Pills making machine (for pills),

(9) Capsule filling and capsule sealing machine (for capsules),

(10) Tablet coating machine (for making coated tablets), and

(11) Instruments required to inspect physical quality (such as disintegrator, harness tester etc.).

(d) For the production of injection:

(1) Machine to prepare pirogen free distill water,

(2) Machine to clean, wash and dry ampoules, vile bottles or containers,

(3) Mixing and preparing tanks,

(4) Autoclaving machine,

(5) Filter to filter without presence of organism,

(6) Filling, sealing and tightening covers,

(7) Inspection machine,

(8) Leakage testing machine,

(9) In the case of drugs required to be produced in an aseptic condition, such means and instruments as decided by the Department.

7. Raw materials:

(1) The quality standards of all kinds of raw materials to be used in the production of drugs have to be fixed under the formal pharmacopeias, other literature or the concerned standards. Such materials have to be used by observing the following matters:

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(a) Test has to be done as to whether such materials are pertinent ones,

(b) Such materials have to be certified after having the same analyzed by the quality control,

(c) Raw materials approved by the quality control have to be labeled as prescribed and placed separately from other materials, and

(d) Such raw materials as appear from testing that they cannot be used in production or they are useless have to be set aside so that they are not used.

(2) Records of raw materials:

Such type of records should indicate, inter alia, name and source (production and batch number) of the raw materials, quantity obtained, date of receipt, date of testing, method of storage, date of approval given by the quality control, quantity used in production, quantity in-stock.

8. **Production work:**

Drug production work has to be done under supervision of and at the responsibility of the expert as mentioned in section 13 of this Code. In producing drugs, attention has to be paid to the following matters:

(a) Prior to the commencement of production, the related tools or instruments or machines or rooms have to be cleaned properly and sterilized as per necessity,

(b) Labels have to be put clearly on all goods, machines, containers used to produce drugs in such a manner to produce related drugs during the period of production.

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(c) A person engaged in production work has to be put on clothes, shoes, cap, mask, gloves and safety gaggles etc. in a manner to cover various organs of the body,

(d) Hands should be washed with sterilizing liquids before entering a room producing parentral drugs,

(e) A person engaged in production work should not be suffering from any communicable disease. The health of such person has to be checked up from time to time,

(f) Written directives of production:

The mode of production and directives to be given in respect of the production of each drug has to be prepared under the supervision of responsible experts. Such written directives should contain the following modes and guidelines in respect of each drug:

(1) Name, composition, type, kind of the drug to be produced, quantity and formula of active ingredients,

(2) Mode of production of the drug,

(3) Putting labels on containers used to store the drug at various stages of drug production, clearly indicating the batch number and name of drug,

(4) The quality, quantity or measure to identify the raw material used in the production of drug should be such that the same may be identified at any time after the production or during production,

(5) The quality control, method of testing and analysis and description required to be done or made at each stage of production, and the name of section performing these acts and post of the concerned persons should be clearly mentioned, and

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(6) Directive relating to the storage of semi-prepared and prepared drugs.

(g) Unrelated drugs or materials should be placed distinctly in a separate space in a room where production of any drug begins,

(h) Production work should begin with proper method and care according to the method to be followed for the production of drugs to be sterilized. Labels should be clearly put on those matters to be used in such drugs have already been sterilized and those which are yet to be sterilized,

(i) Acts of weighing, mixing, making dust, making tablets or putting capsules of pesticide drugs and antibiotics should be done in separate rooms, and proper provisions should be made to let air go outside from these rooms separately,

(j) Batch records of production:

The records of production should contain full accounts and description of each batch of any drug. The records of production should indicate as to whether the drugs has been produced in full compliance with the production method, whether test has been done or not and the name of person doing and making test and analysis. In addition to the records of production, distinct batch record should also be prepared and maintained safely for at least five years. The batch records should include the following matters:

(1) Name, composition and formula of the drug,

(2) Date of commencement of production,

(3) Date of completion of production,

(4) Number or code giving information of batch,

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(5) Quantity of raw materials used in the batch and method of identification,

(6) Quantity of theoretical production to be achieved at each stage and quantity of practical production achieved.

(7) Records regularly signed indicating the method and precaution followed at each stage of production and special matter, if any, having come to the attention or been noticed,

(8) Processes followed to control production and results thereof,

(9) Specimen of actual label,

(10) Description of machines used in production, period thereof and packing materials,

(11) Signature of expert responsible for production, and date,

(12) Report of the quality control giving full information as to whether the drug of the concerned batch conforms to the prescribed standards or not.

(k) Labels have to be put as prescribed by the Act and rules on the produced drugs, and

(l) The label of a produced drug should indicate the date of production and expiry date, as required.

9. Quality control:

Each industry producing drugs have to make a provisions of a quality control unit of its own, with responsibility being entrusted to it independently, for the quality control of such drugs. Its main function is to maintain quality-standard and stability of any raw materials to be used in

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the production of drugs, drugs being produced and drugs produced, and its duty is to render various assistance for the quality control in the process of production of drugs. There must be a laboratory under it. The laboratory shall have employees and instruments in an adequate quantity for the test and analysis of quality of the drugs being produced or the drugs already produced. Under this kind of provision, the process of the minimum quality control as specified by the Department can be conducted by the concerned industry itself and the other special kind of quality control can be carried out through any other laboratory approved by the Department.

10. Instruments required for quality control of drugs:

Such methods and instruments required for evaluation of quality standards or control of quality of any drugs shall be as mentioned in the Nepal pharmacopeias, such other literature and standards as may be approved by the Department.

11. Quality control process:

The quality controller should perform the main functions as follows:

(a) To prepare detailed methods or information for the performance of test or analysis of each drug,

(b) One who performs the test, analysis of the raw materials to be used in each batch is to give approval to use the same in production,

(c) To perform the test and analysis of the semi-processed drugs in each batch and give approval to go ahead in production work,

(d) To perform the test and analysis of the prepared drugs and give approval to store or sell and distribute such drugs,

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(e) To control the materials to be used to pack and label drugs and the materials to be used in the final packing and give approval to bring them in use,

(f) To evaluate the situation of storage of any raw materials, semi-processed materials or produced drugs,

(g) To evaluate the quality and stability of any raw materials, semi-processed materials or produced drugs,

(h) To fix the expiry date of produced drugs and standards related with change that may occur in drugs when they are put in shelf,

(i) To fix internal methods as to quality control,

(j) In order to properly bear the responsibility within own purview, the quality control is to collect required samples in accordance with proper procedures for the analysis and label the same and safely retain some portions for the future analysis, and

(k) To collect, from time to time, samples of even the drugs already sold and distributed and do study on quality standards and stability.

12. Records of test and analysis:

Such records or record book should contain the following matters:

(a) Results of analysis of raw materials and production process made at various stages and decision as to whether final evaluation of the produced drugs and test and analysis of the standards of the drugs concerned have been performed or not,

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(b) Details of methods and standards used according to the formal literature or approved analytical method,

(c) Signature of the person performing analysis and test, and

(d) Date of review made by the responsible expert and his/her signature.

13. Packing and label:

Only the concerned person or another person only in presence of such person shall be allowed to enter the room where label and packing materials are stored. Label and packing materials shall be distributed in the required number only in order to prevent mistakes in making labels and packing; and only the concerned persons shall be allowed to use such materials. Prior to labeling and packing the drugs of any batch, the quality controller should give approval to pack such drugs. Only the concerned person should draw the packing and labeling materials from the storage only after properly checking the same as per the requisition form submitted by the expert. The requisition form should bear the signature of requisition maker, and clearly indicate the type and quantity of the labels and packing material requested and the date. The number of the remaining unused labels and packing materials should be worked out by comparing the number of packing materials and the number of those obtained by requisition form. Necessary provisions should be made and action taken to destroy those labels and packing materials which cannot be used. If there is any shortfall in any labels and packing materials, an inquiry should be made thereinto.

A label to be put on a prepared drug should contain at least the following matters:

(a) Name and quantity of the drug,

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(b) Production permit number,

(c) List (along with quantity) of active ingredient or ingredients,

(d) Batch number,

(e) Date of production of the drug,

(f) Expiry date (in the case of a drug, as required),

(g) Information on the situation of storage and necessary precaution,

(h) Method of use,

(i) Name and address of producer,

(j) Group of drug,

(k) Name of drug in the Devnagari script.

14. Records of sale and distribution to be maintained by producer:

For marketing any drugs produced, records clearly indicating the necessary details of such drugs have to be maintained. If any drug is to be recalled, such records should be of such as to make help.

15. Other records:

Proper records of those drugs which have been returned, recalled, expired, destroyed, or otherwise produced in a manner to be non-qualitative and unsafe for the human being have also to be maintained. Where any drug, out of the drugs so produced, records indicating its decision, date of processing, method of processing and re-sale and distribution have also to be maintained.

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16. **Technical employee:**

(1) A person who establishes any drug industry has to make provision of at least one expert having possessed the following qualification in order to look after the process of drug production:

(a) Bachelor's degree in pharmacy, or

(b) Master's degree in pharmaceutical chemistry, or

(c) Having done master's degree in chemistry and gained three years of experiences in drug production works.

(2) A person who establishes any drug industry has to make provision of at least one expert having possessed the following qualification in order to look after the quality control of drugs:

(a) Bachelor's degree in pharmacy, or

(b) Master's degree in pharmaceutics or chemistry.

17. **Miscellaneous:**

(a) All types of records and record books have to be maintained properly.

(b) Employees in the required number have to be employed for the production or analysis works.

(c) Where it is known or a report is received that any kind of loss or adverse effect has be resulted from the consumption of a drug produced, the producer has to review the quality and production process thereof and take required precaution promptly,

(d) Test, analysis and evaluation have to be carried out properly in order to sell and distribute the returned or recalled drugs by re-processing the same,

(e) The producer has to form a team of experts and get evaluated the control of quality of drugs and production control acts, from time to

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(f) Such instruments and machines as may be prescribed by the Department have to be used to produce the drugs falling outside the category mentioned above or the drugs of other composition.

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