

Testing and Acceptance Measures for the Standard Examination of Quality Management in the Production of Animal Medicines

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For the purposes of further standardizing the examination and acceptance of the animal medicine GMP, and quickening the implementation of the animal medicine GMP, the Ministry of Agriculture revised the "Testing and Acceptance Measures for the Standard Examination of Quality Management in the Production of Animal Medicines" (hereafter referred to as "Measures") according to "Measures for Animal Medicine Management" and "Standards for Quality Management in Animal Medicine Production". The "Measures" are now publicized, and will be implemented as of June 1, 2005. In the mean time, the previous "Measures for the Test and Acceptance in Animal Medicine Production Quality Management Standard Examination" (Announcement of Ministry of Agriculture No.267) shall be annulled. The related issues are announced as follows:

1. As of June 1, 2005 the static examination for the animal medicine GMP will be cancelled; for the manufacturers that have passed the test and examination, the term of validity for the "Animal Medicine GMP Certificate" will be five years.
2. After newly established manufacturers get the "Animal Medicine GMP Certificate", they should, in accordance with "Animal Medicine Management Regulations" and "Measures for the Management of Animal Medicine Product Approval Numbers", apply for the "animal medicine production permit" and a product approval number.

After a renovated or expanded enterprise gets the "Animal Medicine GMP Certificate", it should, in accordance with "Animal Medicine Management Regulations" and "Measures for the Management of Animal Medicine Product Approval Numbers", apply for changing the "animal medicine production approval" and obtaining approval numbers for new products.

3. Ministry of Agriculture will only issue product approval numbers to products whose scope is indicated in the "Animal Medicine GMP Certificate", and have been produced according to the national standard of animal medicine. For a product that has been produced by a newly established enterprise for production test and approval, once the product has been tested and approved by a legal testing organization, it can be treated as a qualified product after obtaining the product approval number and whose type and quantity of the test production being approved by provincial animal medicine administration; but such products must have an expiration date that complies with the standard of the state animal medicine, and must be sold and used before the expiration date.

Any product that is not regulated by the state animal medicine standard will be regulated by the "Measures for Animal Medicine Registration".

4. To obtain the consistency of the management of animal medicine GMP and a smooth transition of policy, the enterprises that have passed the animal medicine GMP static examination before June 1, 2005 must submit an animal medicine GMP implementation report to its provincial veterinarian administration 3 months before the expiration of the "Animal Medicine GMP Certificate".

The provincial veterinarian administration should complete a supervision and examination of the enterprise's implementation of GMP within 20 working days after receiving the report, and provide an opinion. The supervision and examination report and the opinion should be reported to the Ministry of Agriculture and the ministry's veterinarian medicine GMP working committee office.

Based on the supervision and examination report and relevant regulations, this ministry will issue the "Animal Medicine GMP Certificate" and relevant administrative licensing.

5. The "Animal Medicine GMP Certificate" is the pre-condition for an enterprise to obtain the "animal medicine production approval" and begin animal medicine production. According to the regulations of the "Animal Medicine Management Regulations", for the enterprises that have violated the regulations for GMP, the Ministry of Agriculture will make punishment decisions such as warning, stopping production for rectification, or canceling the enterprise's "Animal Medicine GMP Certificate" and "animal medicine production approval" depending upon the circumstances of violation.

April 27, 2005

Testing and Acceptance Measures for the Standard Examination of Quality Management in the Production of Animal Medicines

Chapter I General Provisions

Article 1 For the purposes of standardizing the examination and acceptance of the animal medicine GMP, these "Measures" are formulated according to the regulations of "Measures for Animal Medicine Management" and "Standards for Quality Management in Animal Medicine Production" (hereafter referred to as animal medicine GMP").

Article 2 The Ministry of Agriculture is responsible for the state animal medicine GMP management and the mutual recognition in international animal medicine trade.

The provincial veterinarian administrations are responsible for the animal medicine GMP training, technical guidance, supervision, examination and management in their respective jurisdiction.

Article 3 The Ministry of Agriculture animal medicine GMP working committee office (to be referred to as "animal medicine GMP Office") is responsible for organizing the acceptance and examination of the animal medicine GMP application materials, on site examination and acceptance, daily management, and relevant tasks given by the Ministry of Agriculture.

Chapter II Application and Examination

Article 4 Newly established (including enterprise that has already obtained animal medicine production approval, but is planning on adding new product for production) or expanded animal medicine GMP enterprises should submit applications for the animal medicine GMP examination, testing and acceptance.

Article 5 Applicant enterprises for the animal medicine GMP examination and acceptance should fill in the "Application for the Animal Medicine GMP Examination and Acceptance" (see attachment 1), and follow the following requirements to submit a copy of written as well as a copy of electronic application materials to the animal medicine GMP office (in the electronic materials, all the production, examination, and management documents should be included):

I. Newly established enterprises

1. General information about the enterprise;
2. The type, type, and product catalogue of the animal medicine planning to be produced;
3. Enterprise organization chart (must specify the name, title of the person in charge, and the function for each department, as well as the interrelationship among the departments);
4. Resumes of the enterprise leader and the department leader; personnel chart for professional technicians and workers in the production, examination, and warehousing stages (including their education and titles) with their departments and positions specified; the technician/total personnel ratio chart for senior, middle level, and lower level technicians;
5. Peripheral environmental chart for the enterprise; the plane map for the enterprise; the warehouse plane map; plane map for the quality inspection area and the plane map for the arrangement of instruments and other machines;
6. Workshop information and plane map for technology layout (including changing rooms, restrooms, passages for personnel and for goods, air brake, the directions of personnel flow and flow for goods, and degrees of air cleanliness); plane map of the air cleaning system, including air inflow, air return, and air drain; plane map of technological equipment.
7. The technology process chart and main process control points for the animal medicine planning to be produced, controlled projects, and the document catalogue for the production and quality control management;
8. The test and approval reports for the main production process, main equipment, water-making system, air cleaning system, testing instruments and equipment, and product technology;
9. Testing report for the testing instruments and meters, measuring instruments, and weighing apparatus;
10. Clean room testing report issued by a lab recognized by the Ministry of Agriculture;
11. Other animal medicine GMP management document catalogue and relevant copies of records and documents.
12. Production equipment and facilities, testing instrument and equipment catalogue (must specify standards, type, and main technical parameter);
13. Animal medicine GMP operation report; and
14. Copies of production approval and testing approval record for the test production of state standard animal medicine (each production line should select 2 to 4 representative types of certain form of medicine, each type should contain the record for at least 3 batches; if any form of medicine has less than 2 types or if the medicines are classified as special product or material medicine, then record for the type that is being produced should be provided).

II. Renovated or extended enterprises

For the renovated or extended enterprises, the following materials must be provided besides the materials mentioned in items 1-13 above:

1. Copies of "animal medicine production approval" and "Operation Certificate for Enterprise";
2. The enterprise's self examination report (including enterprise information, GMP implementation report);
3. Catalogue of products that have been approved for production, document catalogue for the management of production and quality, standardization of products, and product approval documents (including copies of product approval number and quality standard); and
4. Animal medicine GMP operation report and copies of batch production and batch testing record (the requirement is the same as those mentioned in I(14) above).

Article 6 The animal medicine GMP office should finish the examination of the materials within 20 working days after receipt of the application materials. If the examination is passed, the animal medicine GMP office should organize examination and testing on site. If the enterprise fails to pass the examination, then the animal medicine GMP office should send a written notice to the enterprise and require it to add relevant materials to the application within 4 months. If no added application materials are sent in after 4 months, the enterprise will be deemed to have withdrawn their application.

Chapter Three On-site Examination

Article 7 If the application materials have passed the examination, the animal medicine GMP office will issue a "notice of on-site examination" to the applicant enterprise, appoint examination group members, and organize on-site examination and test in the specified time period.

Article 8 The examination group members will be selected from the animal medicine examiner pool of the Ministry of Agriculture; relevant experts can be temporarily invited to attend the examination and test when necessary. The examination group is consisted of 3 to 7 members. A team leader is appointed. The team leader will be appointed by the animal medicine GMP office.

The provincial veterinarian administration and animal medicine supervisory organization within the applicant enterprise's jurisdiction could select a staff member as an observer in the examination, but will not involve in the assessment of the examination.

Article 9 Two meetings will be organized during the on-site examination; a temporary meeting could be organized when necessary; the meetings will be presided by the team leader of the examination group.

The first meeting should confirm the on-site examination plan (see attachment 2 for the format of the plan), scope of examination, examination route, and the examination schedule; principles for the examination and things to be noticed should be declared. The applicant enterprise should provide necessary materials to truthfully introduce their situation, and appoint a liaison to explain the enterprise's situation to the examination group on site and answer questions.

The last meeting will be held to declare to the applicant enterprise the result of the general assessment, projects that need to be improved, and suggestions for improvement. The applicant enterprise can express their opinions on the result of the general assessment and projects that need to be improved; if necessary the examination group should submit the written opinion of the applicant enterprise to the animal medicine GMP office.

Article 10 During the examination, the examination group should strictly comply with the animal medicine GMP and "the Assessment Standard for the Examination, Testing and Acceptance of Animal Medicine GMP". Proof materials should be taken when necessary. The group should

examine relevant personnel of the applicant enterprise (workshop) on their technical operation, theoretical basis, rules and regulations, and the main content and main points of animal medicine regulations and animal medicine GMP.

Article 11 Based on necessity, the group leader for the examination may convene a temporary meeting. The examination group members should report on their research and sample testing, conduct ample discussion on projects that need to be improved and on other problems; they should also listen to the applicant enterprise's explanations if necessary.

Article 12 The examination group members should truthfully record the examination and existing problems. The group leader should organize the general assessment, fill out the table for projects that need to be improved (see attachment 3 for the table format), fill out the on-site examination report (see attachment 4 for the format), and give out the result of the general assessment such as "recommend", "delay recommending", or "not recommend". The table for projects that need to be improved should specify the existing problems and detailed suggestion for improvement. The on-site examination report must describe the applicant enterprise's GMP implementation and specify issues that need to be clarified in an objective, truthful, and accurate manner. The on-site examination report and the table for projects that need to be improved must be signed by all the members of the examination group.

During the general assessment, non-members of the examination group should keep away from the examination site.

Article 13 Materials such as the on-site examination report and the table for projects that need to be improved should be separately preserved by the examination group, applicant enterprise, and the provincial veterinarian administrations.

Article 14 For an applicant enterprise that has received a "recommend" for their assessment, but still needs to be improved, it should provide an improvement plan and organize for its implementation. After the completion of the reform and improvement, the applicant enterprise should submit a reform and improvement report to the animal medicine GMP office. The report should be confirmed by the provincial veterinarian administrations. The animal medicine GMP office should mail the reform and improvement report to the leader of the examination group; the leader should confirm the implementation of the reform and improvement, and fill out the "Examination Table for the Reform and Improvement of Animal Medicine GMP Enterprises" (see attachment 5).

Article 15 For an applicant enterprise that has received a "delay recommending" for their assessment, the animal medicine GMP office will issue a "notice for reform and improvement with a time limit". After the completion of the reform and improvement, the enterprise may submit an application for examination, testing, and acceptance to the animal medicine GMP office. The animal medicine examination group should conduct on-site examinations on the projects that need to be improved and the opinion for reform and improvement, and formulate an examination report.

Article 16 For an applicant enterprise that has received a "not recommend" or an enterprise that received "delay recommending" for their assessment but failed the re-examination, the animal medicine GMP office will issue a "notice of examination failure"; no application from these enterprises may be accepted within 6 months after the issuance of the notice. If a re-application is received after 6 months, it will be processed according to the regulation of Chapter Two and Chapter Three of the present "Measures".

Chapter Four Examination, Approval, and Management

Article 17 The leader of the examination group should submit two copies of the same on-site examination plan, on-site examination report, projects with room for improvement, grading chart,

the Chinese and English title for the enterprise, address, and other related materials to the animal medicine GMP office within 10 working days after the end of the examination work.

Article 18 The animal medicine GMP office will publicize the result of the examination for the enterprises that have passed the GMP examination and acceptance on the website of China Animal Medicine Information. The term of the publication is 5 working days. In this term, any enterprise or individual may raise related issues for discussion. If the publication term has passed without disagreement, a copy of the materials will be submitted to the Ministry of Agriculture.

Article 19 The Ministry of Agriculture will complete the examination of the materials within 20 days after receiving the materials. If the requirements have been met, the Ministry of Agriculture will approve the application, issue a public notice, issue the "animal medicine GMP Certificate", and send the "Animal Medicine GMP On-site Examination Work Feedback Chart" to the enterprise (see attachment 6).

If the enterprise has failed to meet the requirements, the result and opinion will be sent to the applicant enterprise and the animal medicine GMP office.

Article 20 The term of the "animal medicine GMP Certificate" is 5 years. If any change took place within the term such as changing the name of the enterprise, the enterprise should, in accordance with the Measures for Animal Medicine Management, apply to the Ministry of Agriculture for changing the "animal medicine GMP Certificate" and "animal medicine production permit", and submit application report and related materials.

Article 21 Every year the provincial veterinarian administrations will implement periodical supervision examination on the GMP enterprises in their locality. The main content of examination will include the implementation of GMP, the operation of equipment, and whether the records kept are in compliance with related regulations and requirement. The result of the supervision examination will be submitted to the Ministry of Agriculture and GMP office before the end of the year. Serious violations of rules and regulations will be reported to the administration at a higher level.

The Ministry of Agriculture may implement supervision examination on GMP enterprises according to necessity.

Chapter Five Conditions and Qualifications for the Examiner

Article 22 The animal medicine GMP examiner should meet the following conditions:

1. Obeying the laws and regulations, honest in performing his/her duties, insisting on principles, seeking truth from facts, and fair and just;
- 2 Familiar with animal medicine management rules and regulations, animal medicine GMP and relevant technical standards;
- 3 Having obtained associate degree or above in medicine, veterinarian or related fields, or obtaining a middle level title or above, and having been employed for more than 5 years in animal medicine administration, animal medicine supervision, or teaching and research positions;
- 4 Accurately understanding the animal medicine GMP standards and animal medicine GMP examination and acceptance assessment standard and related rules and regulations; and
- 5 Enjoying good health, obeying arrangement, capable and actively participating in the on-site examination.

Article 23 The animal medicine GMP examiner will first be recommended by his/her employer, then he/she will pass the examination after attending the training of the animal medicine GMP office, after which he/she will be listed in the pool of animal medicine GMP examiners.

Article 24 The animal medicine GMP examiner must comply with the rules and regulations of the on-site animal medicine GMP examination. The Ministry of Agriculture will dismiss the GMP examiners who do not comply with the rules and regulations, cannot perform their duties normally, cannot understand the working principle, or do not attend the examination and acceptance activities without reason.

Chapter Six Supplementary Provisions

Article 25 These Measures will be implemented as of June 1, 2005. In the mean time, the "Measures for the Test and Acceptance in Animal Medicine Production Quality Management Standard Examination" (Announcement of Ministry of Agriculture No.267) publicized by the Ministry of Agriculture on April 10, 2003 will be annulled.