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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 15193.24-2014

**National Food Safety Standard -- Food Safety -- Requirements
on Pathology Examination Technique in Toxicological
Evaluation**

食品安全国家标准 食品安全性毒理学评价中病理学检查技术要求

(English Translation)

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1 Scope

This standard specifies the food safety toxicology evaluation routine pathological examination of the technical requirements.

This standard applies to food safety toxicology evaluation routine pathological examination.

Objective 2

By pathological examination of the technical requirements of regulations and standards inspection by the operator, reduce the deviation of test results, so histopathology the results are more scientific, effective and conducive to the accumulation and comparison of scientific data between laboratories provide morphological food toxicology safety evaluation Evaluating the evidence.

3.1 General observation

Supplemented by the naked eye or using a magnifying glass, ruler and days equal tools Specimens and disease traits were observed and recorded findings of process.

3.2 Sampling

Removal of the test animals at autopsy organs and tissues of all or part of the cut whichever representative lesion to use for pathological examination specimen.

3.3 Fixed

The sample specimen is immersed in fixative, so that the material within the cells as close as possible the process of morphology and location of its living state.

3.4 Coverage

Sampling from the pinned specimens in accordance with the purpose and requirements of the pathological process of tissue cut out of the appropriate size.

3.5 Dehydration

The fixed tissue repair after cutting through a series of substitutions dehydrating agent impregnated moisture in the tissue, so that the embedding medium can penetrate into the tissue process.

3.6 Transparent

After tissue dehydration, and both are immersed in a dehydrating agent but also with embedding medium-miscible solvent in the process of embedding agent immersed tissue blocks.

Baptist wax 3.7

After the transparent tissue, in different melting points, density gradient melted paraffin impregnation process.

3.8 Embedded

After soaked tissue penetration agents, (usually paraffin) package process is by embedding medium.

3.9 Slices

Embedded tissue blocks after sliced on a slicer, adhesion process on a glass slide.

3.10 Dyeing

To determine the normal tissue or cell structure or lesion structure, using the corresponding display these dye components, through a series of special place Li, the dye with the tissue or cell components, and to improve the observability of the specimen.

Pathological examination of the general requirements 4

4.1 Personnel requirements

4.1.1

pathology staff by the head of pathology and pathology technical staff, pathology staff should have good professional ethics, science Rigorous work attitude, be able to use our expertise to complete the job.

4.1.2

pathology responsible person should have a medical or veterinary pathology background, with knowledge of pathology and pathological diagnosis empirical theory can be to accurately read the piece were familiar with pathology reporting process and histopathological evaluation of tissue sections responsible, including the abnormal tissue changes Kam Given and explained.

4.1.3

pathology technician should have a medical, veterinary or biological background, or experience relevant test, pathological examination after training, proficiency Master the basic techniques of pathology. At work should be strictly implemented standardized technical procedures.

4.2 Accommodation and environmental conditions require

4.2.1

General pathology laboratory work area according to the quality control requirements should have a separate room or functional areas, including specimen storage room, drawing room, Frozen section room (zone), conventional tableting pretreatment (tissue dehydration, transparent, dipping wax, embedded) room (zone), conventional tableting (sliced, stained, were mounted) room (Region), histopathological diagnosis room, pathological data archives.

4.2.2

The laboratory shall have good ventilation and lighting equipment, emergency power supply and equipped with personal protective equipment sterilization, emergency care facilities.

4.2.3

pathological examination of the relevant equipment should be the appropriate inspection, maintenance, and other operations scrap management procedures.

4.3 Technical Requirements

4.3.1

Acceptance by the person responsible for pathological tissue inspection, check the relevant information and records.

4.3.2

pathology specimen preparation and examination process, should be strictly in accordance with the appropriate standard operating procedures (SOPs) to operate.

4.3.3

by a pathologist who is responsible for microscopic observation, understanding the pathology report issued before the trial-related information, including experimental design, by Physical and chemical properties and biological activity of the test substance characteristics, given the way the test substance, the dose and duration of animal species, strain, weeks, clinical table Now, biochemical and physiological indicators.

4.3.4

In order to obtain a reliable pathological findings, all tissue sections were evaluated with an animal testing required by the responsible person with a pathological Press According to uniform standards, the pathological changes diagnosis and classification. The outer and inner body or bodies, if necessary by pathologist for review.