

## Results of Basic Studies of Vitalliver Suppository

### Acute Toxicity, Long-Term Toxicology, and Liver, Kidney, Non Toxic Side-Effect Tests and Study Reports

#### 1. Acute Toxicity Test Reports

Testing Centre: Laboratory Animal Centre of West China University Medical Science, Sichuan, China

##### Summary:

- Vitalliver suppository was used in Kunming white mice for acute toxicity test: the general condition of animal was good, pathology observation showed no significant change, indicated that Vitalliver suppository is non-toxic and safe for use.
- Vitalliver suppository was administered into Kunming white mice rectum for acute toxicity test: the maximum dosage in the highest concentration of the preparation was administered, showed without causing the animal's death,  $CD_{50}$  was not detected. It was said that Vitalliver suppository is non toxic and safe.
- Vitalliver suppository was administered into domestic rabbit rectum for toxicity and irritable test: there was no toxic symptom appeared in the body of the animal, and without irritable reaction appeared in rectum's mucous membrane.
- Acute toxicity test of Vitalliver suppository: the maximum tolerance when administered into the rectum via anus amounted to 45.33g original drug/kg. (500 times the human dosage of 0.0916 original drug/kg.) So, normal administration of the drug is safe.

#### 2. Long-Term Toxicology Test Reports

Testing Centre: Pharmacology Studies Center, Department of Pharmacy, Zhongshan University, China (Guangzhou)

##### Summary:

- Vitalliver suppository does not have significant abnormalities or toxic reactions to the growth and development, erythropoiesis or biochemical indicators of mice.
- The dissection and histological study on the major organs also showed no toxic reactions or pathological changes. These imply that Vitalliver suppository does not have toxic side-effects and are safe for use.

#### 3. Liver and Kidney's Non Toxic, Side-Effects Test Reports

Test Centre: Department of Microbiology, the University of Hong Kong

##### Summary:

- Vitalliver suppository does not have any significant side-effect towards liver and kidney functions of human body.

## Immunity Function Test Reports

Testing Centre: Laboratory Animal Centre of West China University Medical Science, Sichuan, China

### Summary:

- **Effect on humoral immunity of mice**

Summary: BALB/c mice were given Vitalliver suppositories through intestines for half-month; the humoral immune function was tested by PFC. The result shows that Vitalliver suppositories can significantly ( $p < 0.01$ ) improve the form of PFC at high dosage group, and it can promote humoral immune function to some degree.

- **Effect on the function of T-cells of mice**

Summary: After BALB/c mice were given Vitalliver suppositories through intestines for 15 days, lymphocyte transform index is tested. The experiment shows lymphocyte transform index in middle dosage group is much higher than that in control group. As  $p < 0.05$  in middle dosage group, this group exists a distinct difference.

- **Effect on the activity of NK cells**

Summary: After BALB/c mice were given Vitalliver suppositories through intestines for half-month, NK cells' activity was tested. The result shows that Vitalliver suppository can significantly improve NK activity in high dosage and middle dosage groups. Statistical treatment showed that there were significant and distinct differences ( $p < 0.005$  and  $p < 0.05$ ).

- **Effect on Phagocytic function of mouse Phagocytes**

Summary: the phagocytic index in the large/medium/small dosage groups were higher than those in the blank/positive drug groups. The results demonstrated that the Vitalliver suppository can intensify the phagocytic function of mice phagocytes to a certain degree. Only in the large dosage group  $p < 0.05$  shows a distinct different after statistical treatment.