

Study No. K920413

Kanglaite Injection - Pyrogen Test

Sponsor: Zhejiang Kanglaite Pharmaceutical Co., Ltd.

Author: Ren Wenlong
Shanghai Institute of Pharmaceutical Industry (SIPI)

PERSONAL INVOLVED IN THIS STUDY

Study Conductors: Ren Wenlong, Yao Yulong

Animal Service Manager: Yan Yonggao

Quality Assurance: Liu Quanhai

Study Duration: 1992.9.10~1992.9.20

1. Introduction

KLT is a white emulsion, which is being developed by Zhejiang Kanglaite Pharmaceutical Co., Ltd. according to traditional Chinese medicine theory. KLT was prepared by extracting the anticancer component from Chinese Herb Coicis Semen Yokuinin with modern technology.

The results of pharmacological study indicated that KLT showed significant antitumor effects against some animal transplantable tumors and human tumors xenograft.

According to the China Pharmacopeia (1990), the pyrogen test was performed to determine whether KLT would meet the requirements for the absence of pyrogen.

2. Purpose

The purpose of this test was to determine whether KLT would meet the requirements for the absence of pyrogen.

3. Test Materials

KLT, a white emulsion, was received from Traditional Chinese Medicine Hospital of Zhejiang Province.

Lot. No. 920707
920708
920806

4. Animals

The healthy, mature, male rabbits were obtained from the Animal Department of Shanghai Institute of Pharmaceutical Industry. The animals were given commercially available pellet diet and tap water ad libitum. The animal room environment was controlled at temperature of 22 to 25°C, relative humidity of 30-70% and a 12hr light/dark cycle. The room temperature varied not more than $\pm 3^{\circ}\text{C}$ from the selected temperature. Animals were housed in suspended stainless steel cages individually and free from disturbances likely to excite them. The animal body weight was 2.10-2.50kg.

5. Methods

The dose of KLT was 5 ml/kg body weight and injected intravenously.

Withhold all food from the rabbits used during the period of the test, inserted the clinical thermometer into the rectum of the test rabbits to a depth of not less than 6 cm, and after 5 minutes, recorded the rabbit's body temperature. Prior to the injection of KLT, determined the temperature of each rabbit every 60 minutes for twice, the difference between two determined temperatures should not exceed 0.2°C , the average of two determined temperatures was taken as control temperature. This is the base for the determination of any temperature increase resulting from the injection of a test solution. The range of control temperature should be in $38.0\sim 39.6^{\circ}\text{C}$. In any one group of test rabbits, used only those rabbits whose control temperatures did not vary by more than 1°C from each other.

Inject into an ear vein of each of three rabbits 5 ml of KLT per kg of body weight slowly within 15 minutes after determination of control temperature. Perform the injection after warming KLT to the temperature of 38°C . Record the temperature at 1, 2 and 3 hours subsequent to the injection. The difference between the highest temperature and the control temperature of the individual rabbit was the rise temperature.

If no rabbit shows an individual rise in temperature of 0.6°C or more above its respective control temperature, and if the sum of the three individual maximum temperature rises does not exceed 1.4°C , the product meets the requirements for the absence of pyrogen.

6. Results

The results of pyrogen test of KLT were as follows:

Tab. Pyrogen test of KLT

Lot. No.	Rabbit No.	Body weight (kg)	Control temperature °C		Average control temperature °C	Dose (ml)	Temperature after injection °C			Highest temperature °C	rise temperature °C	Sum of rise temperature °C
			1	2			1	2	3			
920707	1	2.50	38.7	38.75	38.725	12.5	38.8	38.9	38.95	38.95	0.225	0.95
	2	2.10	39.2	39.1	39.15	10.5	39.2	39.3	39.2	39.3	0.15	
	3	2.20	38.4	38.35	38.375	11.0	38.9	38.95	38.95	38.95	0.575	
920708	1	2.25	39.05	39.1	39.075	11.25	39.3	39.2	39.2	39.3	0.225	0.95
	2	2.23	38.6	38.5	38.55	11.15	38.9	38.85	38.9	38.9	0.35	
	3	2.20	39.05	39.0	39.025	11.0	39.2	39.4	39.4	39.4	0.375	
920806	1	2.10	38.8	38.7	38.75	10.5	39.0	39.1	39.1	39.1	0.35	0.925
	2	2.16	38.8	38.9	38.85	10.8	39.05	39.1	39.15	39.15	0.30	
	3	2.24	39.2	39.05	39.125	11.2	39.3	39.4	39.3	39.4	0.275	

7. Conclusion

The results indicated that KLT (Lot. No. 920707, 920708, 920806) met the requirements for the absence of pyrogen.