

Study No. K920412

Kanglaite Injection Hemolysis Test

Author: Zhou Guoming
Shanghai Institute of Pharmaceutical Industry (SIPI)

Sponsor: Zhejiang Kanglaite Pharmaceutical Co., Ltd.

Shanghai Institute of Pharmaceutical Industry (SIPI)

Personal Involved in This Study

Study Conductors: Zhou Guoming, Shen Jinli

Animal Service Manager: Yan Yonggao

Quality Assurance: Liu Quanhai

Study Duration: 1992.8.1~1992.8.10

Summary

Kanglaite Injection (KLT) is a white emulsion. This test was to determine whether KLT would induce hemolysis. The result indicated that KLT did not induce hemolysis.

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.

2. Purpose

The purpose of this study was to determine whether KLT would induce hemolysis.

3. Test Materials

KLT, a white emulsion (Lot No 920604, 920605, 920606), was received from Traditional Chinese Medicine Hospital of Zhejiang Province on 20 June 1992.

4. Animals

One Japan species rabbit was obtained from the Animal Department of Shanghai Institute of Pharmaceutical Industry. Body weight was 2.8kg.

5. Methods

10 ml of blood was taken from the heart of the rabbit; put in a conical flask with glass pellets, shaken for 10 min. 10 fold saline was added, stirred well and centrifugalized. The supernatant was discarded. The sedimentary red blood cells (RBC) were washed with saline for 2-3 times until the supernatant did not show red color. The red blood cells were diluted with saline and made suspension of 2% red blood cells.

Tube number	1	2	3	4	5	6	7
2% RBC	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Saline(ml)	2.0	2.1	2.2	2.3	2.4	2.5	-
KLT(ml)	0.5	0.4	0.3	0.2	0.1	-	-
Distilled water(ml)	-	-	-	-	-	-	2.5

According to above table, added suspension of 2% red blood cells and saline to tube, put these tubes into incubator for 3 hours (37°C).

6. Results

The results of this test indicated that KLT did not induce hemolysis.