Lab No.:_____

P.O. No.: 2001051**0**

PRODUCTS EFFICACY

LABORATORY REPORT

Test Unit:

Dept. of Pharmacology
School of Pharmaceutical Science
Jilin University
8 Xinmin St.
Changchun, JiLin, China

Sponsor:

Hamida Pharma, Inc.
15041 Bake Pkwy, #E
Irvine, CA92618
U.S.A.

TEST TITLE:

ACUTE ANTI-INFLAMMATORY EFFICACY STUDY OF ARTHRITOL (CARRAGENAN-INDUCED SWELLING TEST)

TEST ARTICLE: ARTHRITOL

Source: Hamida Pharma, Inc., USA

Identification No.: AR-1003

STUDY & SUPERVISORY PERSONNEL:

Shaochun Qu, Xiaofeng Yu, Dayuan Sui

STUDY DIRECTOR:

Xiaofeng Yu, B.M. _____ Date: May, 2002

Study director

APPROVED BY:

Prof. Dr. Dayuan Sui _____ Date: May, 2002

Director of Dept. of Pharmacology

ABSTRACT:

Acute anti-inflammatory test of Arthritol on rats was carried out according to principles of traditional Chinese medicine study. Arthritol can inhibit swelling on rats' sub-plantar hind paw. The anti-inflammatory effect of Arthritol at the biggest dosage group can match that of Aspirin, and the period of anti-inflammatory effect of Arthritol lasts longer than that of Aspirin.

OBJECT: To evaluate the potential anti-inflammatory properties of Arthritol against the inflammatory action of carrageenan injected into the sub-plantar hind paw of a rat. This test is one of the standard methods for evaluating acute anti-inflammatory activity.

TEST ARTICLE:

Arthritol powder supplied by Hamida Pharma, Inc. of the United States.

Identification No.: AR-1003

GENERAL SYSTEM PARAMETERS:

Animals:

Species: Wistar rats

Source: Experimental Animal Center of Jilin University

Certificate: 10-5112

Sex: Male and Female

Age: No particular age was prescribed for this study

Body Weight Range: 180-220 gram

Acclimation Period: 2 days

Number of Animals: 50

Identification Method: fur coloring

Animals Management:

Husbandry: Conditions conformed to Standard Operating Procedures, which are based on the "Guide for the Care and Use of Laboratory Animals".

Food: NIH-07 Rodent diet was provided daily.

Water: Freely available, municipal water was delivered through an automatic watering system.

Contaminants: Reasonably expected contaminants in food or water supplies did not have the potential to influence the outcome of this test.

Housing: Animals were housed in groups of 10 per extract in stainless steel cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

Environmental: The room temperature was monitored daily. The temperature range for the room was within a range of 20-26℃. The room humidity was monitored daily. The humidity range for the room was 40-70%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark.)

Facility: Pharmacology Lab of Basic School of Medical Science, Jilin University is registered with the Ministry of Public Health of PRC and conforms to GLP standards.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, previously unused animals were selected.

Test System Justification:

This test is a standard method for evaluation of acute anti-inflammatory activity and there is a good correlation to activity in man. Compounds working in this test may be considered to have activity comparable to non-steroidal anti-inflammatory drugs (NSDAIDs).

METHOD:

The 50 rats were randomly and equally distributed into 5 groups (10 rats/group), namely Vehicle Control Group and 1g/kg Group, 2g/kg Group, 4g/kg Group, which were separately equal to 5, 10, 20 times of clinical dosage (2g/60kg), and Aspirin 100mg/kg group. Each rat was administrated orally using an appropriate size needle and syringe, 1 time a day, 3 consecutive days. Before experiment right hind paw normal volume (ml) of each rat was measured using a plethysmoneter. 60 minutes later of last dosing, 0.1ml of a 1% suspension of carrageenan is injected into the sub-plantar region of right hind paw under aponeurosis. After injection in succeeding 1, 2, 4, 6 hour in the right hind paw, volume of each rat’s right hind paw was measured using a plethysmometer. The difference of the hind paws volume before and after inflammatory action was swelling degree. Compare the swelling degree of each group.

RESULTS:

Arthritol can obviously decrease paw volume of rat compared with control group. The difference is statistically significant ($p<0.05$, $p<0.01$). Otherwise, 4g/kg group showed the anti-inflammatory efficacy that matches that of Aspirin, and the effective period lasts longer than Aspirin. (See table 1)

CONCLUSION:

A statistically significant decrease in the paw volume in treated rats by Arthritol compared to that of vehicle control is considered that Arthritol have anti-inflammatory activity superior to non-steroidal anti-inflammatory drugs (NSDAIDs), such as Aspirin.

RECORD STORAGE:

All original data pertaining to this study and a copy of the final report are to be retained in Dept. of Pharmacology, Basic School of Medical Science, Jilin University of China.

Table 1. Effect of Arthritol on rats' hind paws swelling（n=10，x±s）

Group	Before injection of Carrageenan	After injection of Carrageenan			
		Volume of Paw			
	Volume of Paw（ml）	1h	2h	4h	6h
Control	1.10±0.08	0.42±0.14	0.66±0.18	0.54±0.15	0.33±0.14
Aspirin	1.12±0.09	0.29±0.10*	0.40±0.17**	0.29±0.16**	0.21±0.13
ARTHRITOL					
1g/kg	1.08±0.05	0.35±0.14	0.48±0.16*	0.39±0.15*	0.30±0.14
2g/kg	1.10±0.07	0.30±0.09*	0.43±0.10**	0.35±0.16*	0.25±0.17
4g/kg	1.11±0.09	0.27±0.15*	0.42±0.12**	0.32±0.15**	0.19±0.13*

Compare with Control group, **p<0.05,**p<0.01