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REPUBLIC OF KOREA

Technical report: Antigenicity test*

Prepared for the Government of the Republic of Korea
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

Based on the work of Minoru Takemoto,
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* This document has not been edited.

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1. Introduction

Based on an agreement with UNIDO, I was engaged in KRICT (the Korea Research Institute of Chemical Technology) for fourteen days as a specialist of Antigenicity study. Antigenicity study which belongs in the field of Immunology and is required in the testing of new drugs in Japan, is one of toxicological evaluation studies of chemicals. And KRICT has been to establish a well equipped research institute for toxicity tests, already invited such as a teratologist and a toxicologist. In this report, I describe my doings, my impression and my findings in KRICT.

2. The persons I met in Seoul and Taejon, Korea

May, 30, 1988 in Seoul

Mr. Park Pyong Chol, UNDP project programmer

Persons I made contact with while I worked at KRICT : in Taejon

- 1) Jung Koo Roh, Ph.D., Director of Toxicology
Research Center, KRICT
- 2) Sang Seop Han, Ph.D., Senior Research Scientist
of Toxicology Research Center, KRICT
- 3) Kim choong Yong, Research Scientist of
Toxicology Research Center, KRICT
- 4) Park Ryong Chol, Research Scientist of
Toxicology Research Center, KRICT

3. Explanatory note

Abbreviation :

KRICT : Korea Research Institute of Chemical Technology

GLP : Good Laboratory Practices

SOPs : Standard operating procedures

ASA : Active systemic anaphylaxis

PCA : Passive cutaneous anaphylaxis

4. Job description

On daily routine schedule, method and mechanisms of antigenicity tests were lectured in the morning and practices of tests were done in the afternoon. The items lectured were as follows : In vivo tests, (1) Active systemic anaphylaxis (ASA), (2) Passive cutaneous anaphylaxis (PCA), (3) Passive systemic anaphylaxis (PSA), (4) Arthus typed skin reaction, (5) Delayed type hypersensitivity, (6) Maximization test, (7) Photosensitivity test. and in vitro tests, (1) Passive hemagglutination test, (2) Schultz-Dale reaction, (3) Precipitation test, (4) Radioimmunoassay (RIA), (5) Enzyme immunoassay (EIA), (6) Migration Inhibiting test, (7) Lymphocyte blast transformation test.

5 . Planning protocol

Content of studies of antigenicity test is changeable in accordance with molecule or properties for example, effectiveness of a test substance. Settlement items on a large scale or on a small scale, dosage, sensitizing schedule, with or without adjuvant and other subjects are very important to plan a protocol of antigenicity test. And some of these items will be select by using one's experience or by use of papers.

6 . Preparation of work sheets

Considering GLP, every raw data which will be obtained from an examination should be kept on recorded.

Form an idealistic view point every data from the examination can be save into a computer memory, however it is realistically difficult for an antigenicity test. Hence, it is necessary that the results from the test are recorded in work sheets, How to design work sheets is important.

Code No., test substance, experimant, day, name and other subjects are need in a sheet.

7. Preparation of SOPs

According to the GLP, each separate laboratory unit should have immediately available SOP relevant to the activities being performed therein.

Prior to carry out a contract study of Antigenicity test in KRICT, he should have prepare SOP of antigenicity test.

By the way, KRICT will be compel to originate SOP of antigenicity test with a long time, owing to be lack of a model, for instance, a guideline of antigenicity test.

I guided trainees in KRICT preparation of SOPs as following.

SOPs for Antigenicity test

1. General Rules

2. Detailed Rules

- (1) Control of Experimental Animals
- (2) Control of Substances
- (3) in vivo Experimental Procedure
- (4) in vitro Experimental Procedure
- (5) Maintenance of Equipments
- (6) Records and Reports
- (7) Additional Data

8. Indication of the problems

8.1 The problems of collecting information

KRICT TOXICOLOGY has to operate contract research from all over the world. And the method is different depending on the purpose of the test of the trustee and the supervising government authorities of the trustee's country. Moreover, there is an occasional adjustment of the experimental method in each country.

Therefore, it is necessary to acquire the information systematically from all over the world at any time.

An especially to carry out an antigenicity test, many sort of reagents, special articles are necessary. It is expected that a information (catalog included) will be established in future.

8.2 Others problem

First, I was mentioned that I should do practice in an antigenicity test. Two men of trainees had not known their own role when I started training. And they had have their own job, they had not have enough time to participate in our training.

Therefore, it was very difficult to carry out training for two weeks all the category of antigenicity test.