

NEW PHARMACOLOGICAL, CLINICAL, MICROBIOLOGICAL AND ANALYTICAL TESTS MADE WITH VARIOUS GINSENG PREPARATIONS OF THE WORLD MARKET

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Already many important studies were made with Korean ginseng roots and their ingredients (saponins, etc.) and they proved that they have very positive effects on the human body.

However, with many of the products of the world market those positive effects cannot be observed and the preparations themselves have shown poor quality.

Since the high quality of ginseng preparations is of utmost importance for the image of ginseng and the acceptance by physicians and health authorities, a study is presented, made with different ginseng products of the world market.

My short speaking time on this symposium today will only allow me to give you a very short information about this subject and about the main investigations which we had done during our large research program we did on ginseng during the last years.

The aims of this research program in which Pharmaton and Ginseng Products Ltd. invested about 3 million US-dollars within a few years were:

- I) To develop ginseng preparations of highest class.
- II) To run large tests and to standardize them.
- III) To compare their effectiveness etc. with other ginseng preparations in the world market (comparison tests).

After aims I and II were reached with the G115-Extract and GINSANA, we started to work on the part III about two years ago and rather sensational results came out.

Basic investigations about purity and cleanliness of products

We have executed microbiological controls with GINSANA and Ginseng Extract G115 in comparison with competitors' products. Also for orally applied preparations (such as capsules, syrups, tablets, etc.) precise microbiological tests should be made by all manufacturers. We would like to mention here some of the most important ones.

Detection of coliform bacteria (enterobacteriaceae)

The presence of a certain number of germs from the family of Enterobacteriaceae must be valued as a warning signal. For instance unsatisfactory production conditions or insufficient hygienic measures.

Only a quantity of up to 100 germs per g or ml in the preparation to be tested is still permitted.

1. GINSANA=OK
- 2-4. Competitor's products indicate the presence of these germs. (Fig. 11)

Selective culture medium for the detection of *Escherichia coli* and coliform bacteria

They are present in the large intestine and in feces of warm- and cold-blooded organisms. Amongst these the bacterium *coli* can be found, a germ causing gastroenteritis and mucous inflammations of the intestinal tract. These germs should never be present.

1. GINSANA = OK
- 2-4. In competitor's products these germs were found. (Fig. 12)

Detection of salmonella

This is the designation for the group of Typhus-Paratyphus and Enteritis bacteria.

These bacteria should never be found in pharmaceutical preparations.

1. Ginseng Extract = OK
2. Competitor's product = OK
3. Competitor's product = Salmonella are present. (Fig. 13)

Pharmacological comparison tests

One of the best methods to measure the effect of a preparation is the mice swimming test (increase of performance).

Different groups of 50 mice each received the ginseng preparation in water solution daily for 28 days and a control group got daily for the same time water without active ingredients. The dosage was according to the relation of the weight between man and mouse. After 28 days treatment the mice were placed into a water bath and allowed to swim until they were completely exhausted.

The statistical comparison of each group with the untreated group gave the following results (Consultox Laboratories, London):

PRODUCT A	MINUS	26.0 %
PRODUCT B	MINUS	16.7 %
PRODUCT C	MINUS	4.6 %
PRODUCT D	PLUS	15.0 %
PRODUCT E	PLUS	16.6 %
GINSANA TONIC	PLUS	21.9 %
G115-EXTRACT	PLUS	51.8 %

For this part of our research program more than 10,000 mice were used in swimming tests under control of international laboratories like Consultox, London, and we have to state that so far no ginseng product or extract, with normal dosages as mentioned above, reached the performance of GINSANA and the G115-Extract PHARMATON.

Analytical tests based on the saponin content

The contents of saponins, as the active ingredients, were analysed in many products too. Here we could find a direct relation between the effect and the content of saponins—provided all main saponins were found in the product, which is not always the case, because the production methods need great know-how.

Clinical studies

Out of the many clinical tests made I would like to present a new clinical study which was just finished and shows very outstanding results. It was quite an expensive and time-consuming study; however, I would recommend such tests to all serious manufacturers, in order to make it possible for physicians and patients to distinguish between good and inferior products.

GINSANA-double blind study

This test was done by Prof. Doerling, Hamburg, Germany, in cooperation with Dr. Kirchdorfer and myself.

GINSANA capsules containing 500mg ginseng, in form of the standardized ginseng extract G115 and placebo (capsules containing pharmacologically inactive ingredients) were used for the study. Dosage: 2 capsules daily. In addition to the experimental investigation, the study also included the questioning of the persons tested.

Sixty persons participated in this double blind test and the composition of the group is illustrated in Fig. 1.

The experimental tests included: determining the reaction time of the test persons with regard to light and sound, assessing the optical merging

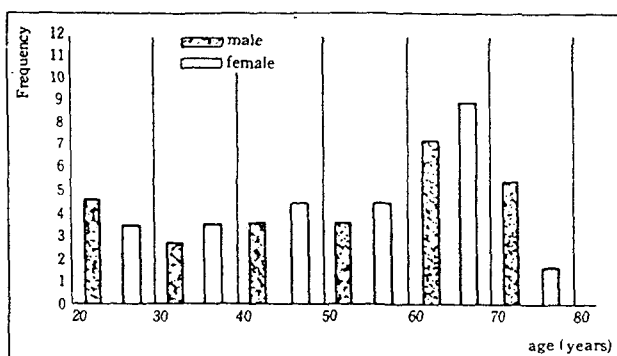


Fig. 1

threshold, determining the co-ordination of both hands as well as the rate of recovery.

In addition, the test persons were questioned before the beginning of the study, after 2, 4, 6, 8, 10 and 12 weeks. The questions were related to the following features: General state and physical condition and performance, mental performance, joy of living/ mood, concentration/memory, as well as sleeping habits

Results

1. Reaction time of the test persons with regard to light and sound impulses

The visual and auditory reaction times were determined. The measurements were taken with the aid of an electronic short-time meter. The data evaluated according to mathematical, statistical

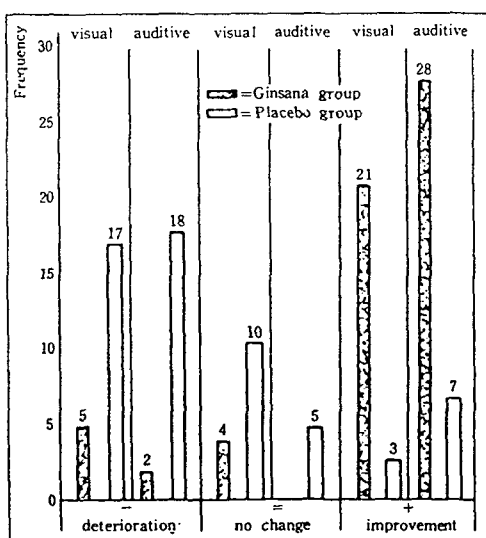


Fig. 2

principles. The results of the measurements are indicated in Fig. 2.

For the group to whom the placebo had been administered, an improvement in the visual and auditory reaction times was only observed in the case of 10 test persons, i.e., only these had a shorter time. For the group to whom GINSANA had been administered, however, an improvement was registered for 49 test persons, i.e., for 81.6% of the group, after three months.

Therefore it must be assumed that GINSANA contributes to revitalisation.

2. Assessment of the optical merging threshold

The optical merging threshold is defined as: the frequency at which periodically recurring light impulses are perceived as always having the same brightness. The higher the merging threshold, the better is the visual performance. Factors affecting this value are: the brightness of the positive phase, the size of the glimmering field, the range of retina stimulated, the age of the test persons and their state of tiredness. A decrease in the tiredness and a change in the ability to concentrate can be detected with this method. The optical merging threshold had a different level for all of the test persons.

Fig. 3 indicates the results obtained for the placebo group, as compared to the GINSANA group. In the case of the GINSANA group, an improvement in the merging threshold was determined for 59.4%. This means that light impulses

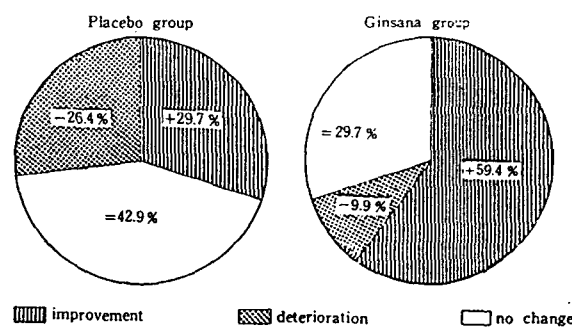


Fig. 3

following each other more rapidly were detected. For the placebo group an improvement was only observed for 29.7% of the test persons.

The conclusion is thus justified, that GINSANA helps to improve the vitality of the aging organism.

3. Assessment of the co-ordination of both hands

We used an apparatus, developed by the American L. Thrustone, with two round metal plates divided in four sections. With this we studied the behaviour of the right hand, the left hand and of both hands (the test person had one contact-stick in each hand with which certain sections of the plates had to be touched). The results for the placebo and GINSANA groups after 4, 8 and 12 weeks are represented in Fig. 4.

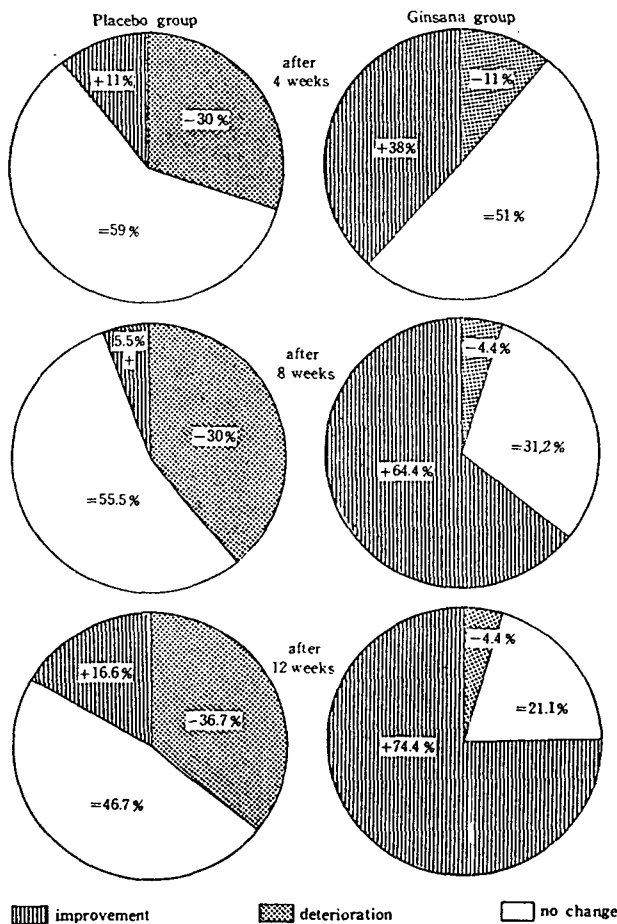


Fig. 4

The table shows a steady improvement from the 4th to the 12th week. In the GINSANA group an improvement in the co-ordination of both hands was only observed for 38% of the group after four weeks. After eight weeks, however, the value rose to 64.4%, and after 12 weeks to 74.4%. For the placebo group an improvement in the co-ordination of both hands was only observed in the case of 16.6% of the test persons.

4. Determination of the recovery quotients

A large part of the testing of the physical performance is based on function tests carried out on individual organs or organ systems, the function of which has an important influence on the ability to work. According to our experience on the assessment of the action and effectiveness of tonics, the analysis of the gas exchange is a good basis for the determination of performance. The body cannot store oxygen. The oxygen consumption thus corresponds to the actual stress situation, so that an integral assessment of the physical performance is possible with an examination of the gas exchange.

For determining the physical performance, we selected a "mounting" test, in which the test person had to go up and down a step, to the beat of a metronome. The oxygen consumption of the test person was recorded during this mounting time of 15 minutes. From the O₂ consumption curve obtained on the recorder, the recovery quotient is calculated from the following formula:

$$RQ = \frac{\text{Increased O}_2 \text{ consumption in the working phase}}{\text{Increased O}_2 \text{ consumption in the recovery phase}}$$

The RQ value obtained for the test person at the beginning of the double blind test, was compared with the value obtained after 3 months. The results are represented in Fig. 5.

An improvement in the RQ value was observed for 29 test persons in the GINSANA group and a deterioration in one case. For the placebo group, an improvement was only found for nine persons, a deterioration for 19 and no change in the case of two test persons.

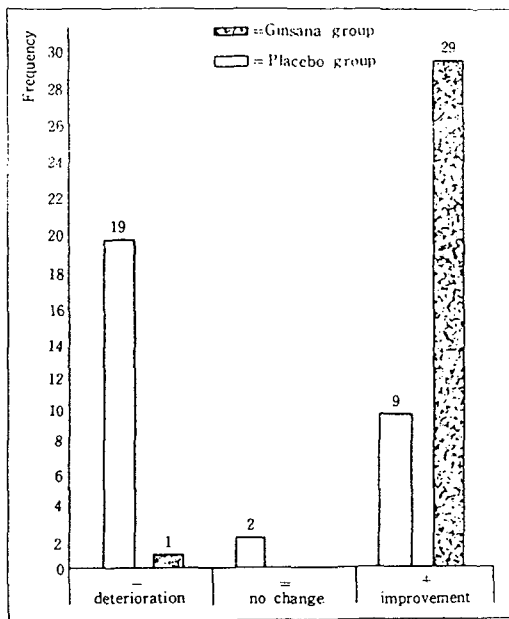


Fig. 5

5. Determination of the recovery period

In assessing the oxygen consumption, conclusions can also be drawn with regard to the recovery period. The oxygen consumption of the test person at rest has a certain value, which increases with the work performed. When at rest again this curve falls as shown in Fig. 6.

The time required to reach the rate at rest can be determined and is known as the recovery period.

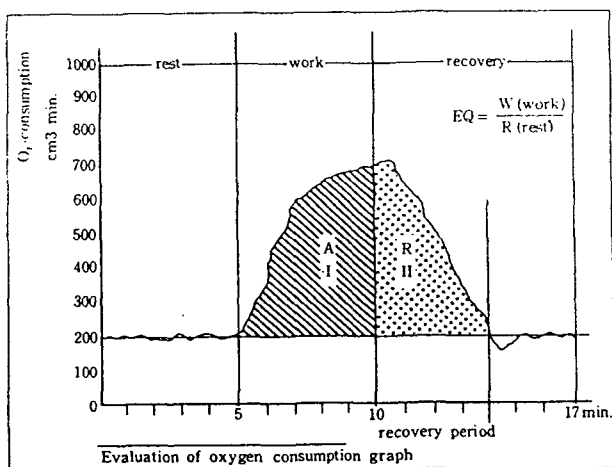


Fig. 6

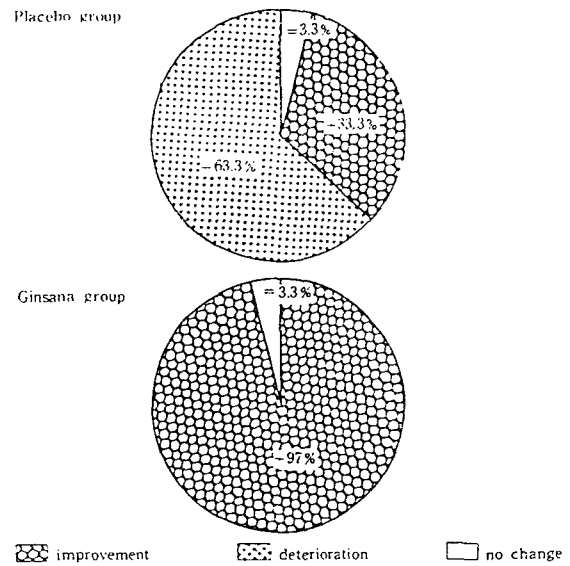


Fig. 7

In Fig. 7 the results of a comparison of the recovery periods before the beginning of the double blind study and three months after the test, are represented. In the placebo group, an improvement i.e., a decrease in the recovery period—was only found for 33.3%. For the GINSANA group, however, the improvement in the recovery period after three months was as high as 97%.

6. The questioning

In addition to the test methods, the persons were also questioned. This was carried out to supplement the objective measurements. We wanted to obtain additional information on the effectiveness of GINSANA, and on the placebo effect, from the self-assessment of the test persons.

The results of the questioning and their percentage evaluation with regard to the frequency of the statements made by the test persons, are represented in Fig. 8.

The results for the placebo group and for the GINSANA group are indicated separately. The figures clearly show that an *improvement in the condition (+)* took place increasingly from the second to the 12th week. No change is indicated for a relatively high percentage of test persons (=) and in a few cases a decrease occurred (-). It is clear

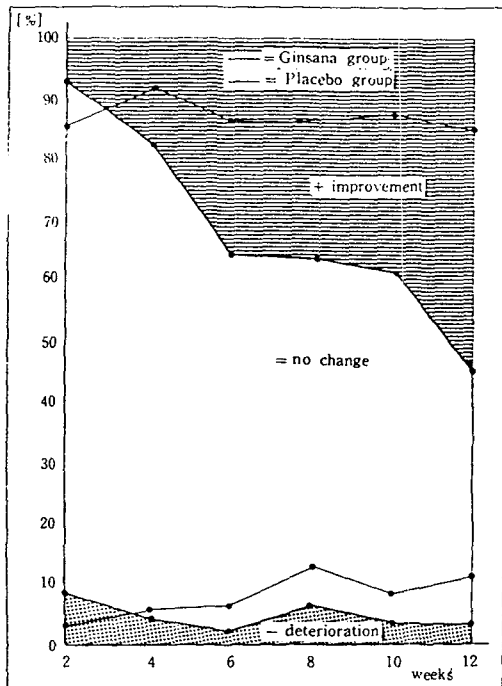


Fig. 8

that the deterioration in the case of the placebo group becomes increasingly larger and that the improvement is only found for about 15%.

Particularly worth remarking on, are the number of test patients within the GINSANA group who experiences a marked *improvement* of their physical capacity. See Fig. 9.

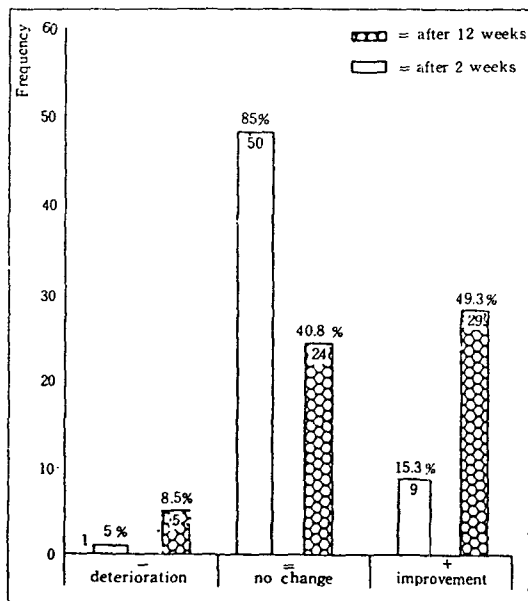


Fig. 9

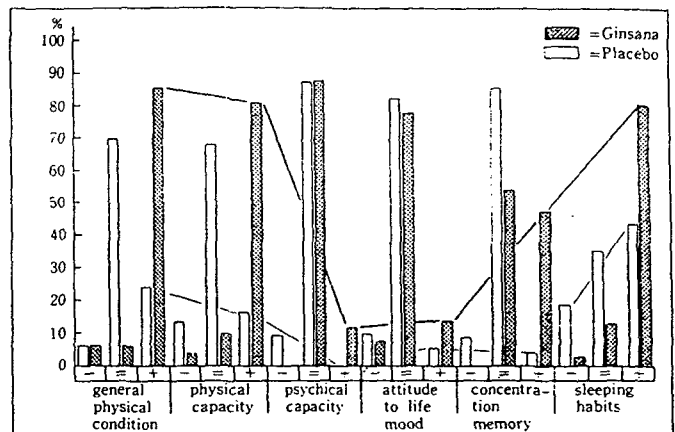


Fig. 10

Fig. 10 illustrates the results of the self-assessment by the test persons after 12 weeks. The results for the placebo and the GINSANA groups are indicated separately for all the characteristics. Here the positive influence of GINSANA can also be seen clearly with regard to the general physical condition, the physical performance, the concentration, memory and sleeping habits.

Summary

The aim of the double blind test was to assess the prophylactic and therapeutic efficacy of the preparation GINSANA, containing the standardized ginseng extract PHARMATON G115. The determination was carried out with special emphasis on the following features: general physical condition, physical performance, mental performance, enjoyment of life/mood, concentration and memory, as well as sleeping habits. Sixty test persons took part in the study, men and women between the ages of 22 and 80. The 90-day test was carried out in the form of a double blind experiment. Experimental measurements were made and the persons were also questioned. The reaction time, the optical merging threshold, the co-ordination of both hands and the recovery quotients, as well as the recovery rates were analyzed. The results for the serum group were clearly better than those for the placebo group, particularly for the characteristics: general physical condition, physi-

cal performance and sleeping habits. The results of the test methods used, especially with regard to the reaction time, the co-ordination of both hands, the recovery quotient and the recovery period, permit the following conclusion to be drawn:

when administered for several weeks, GINSANA has a positive action, in the sense of an activation of the entire personality by the ginseng glycosides contained in the standardized Extract G115.

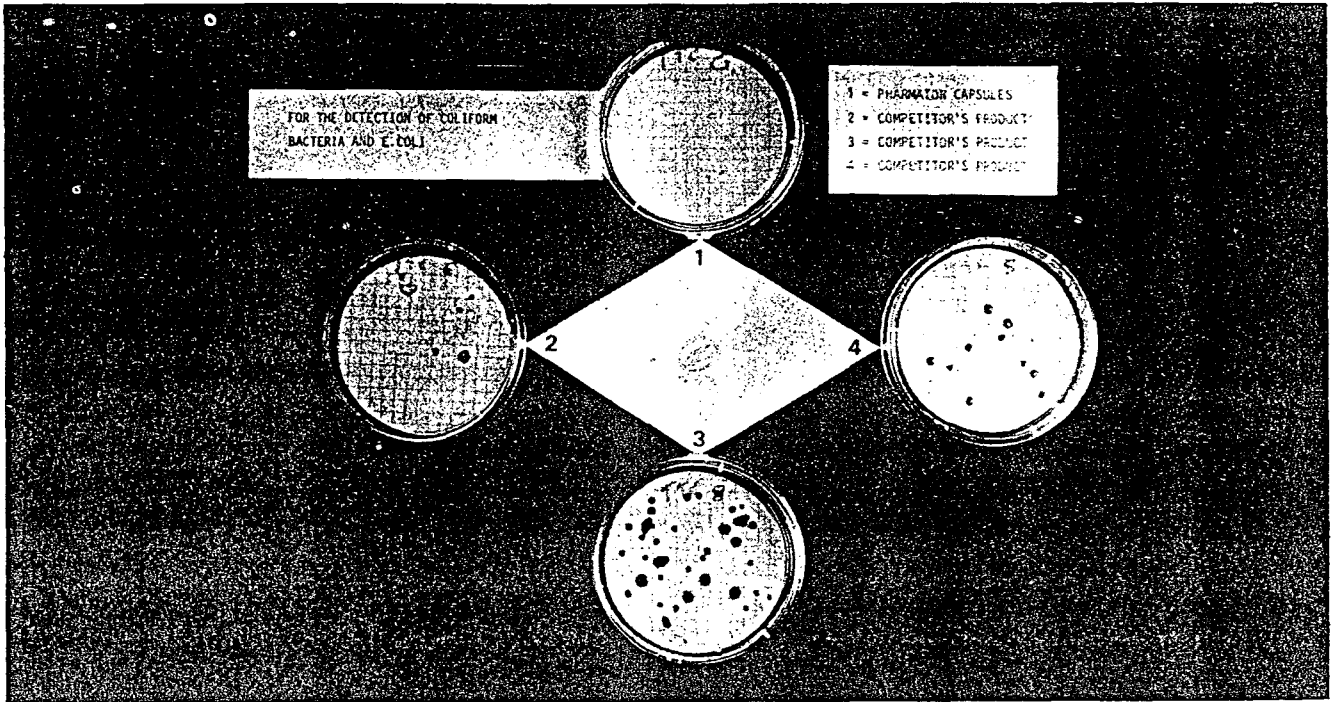


Fig. 11

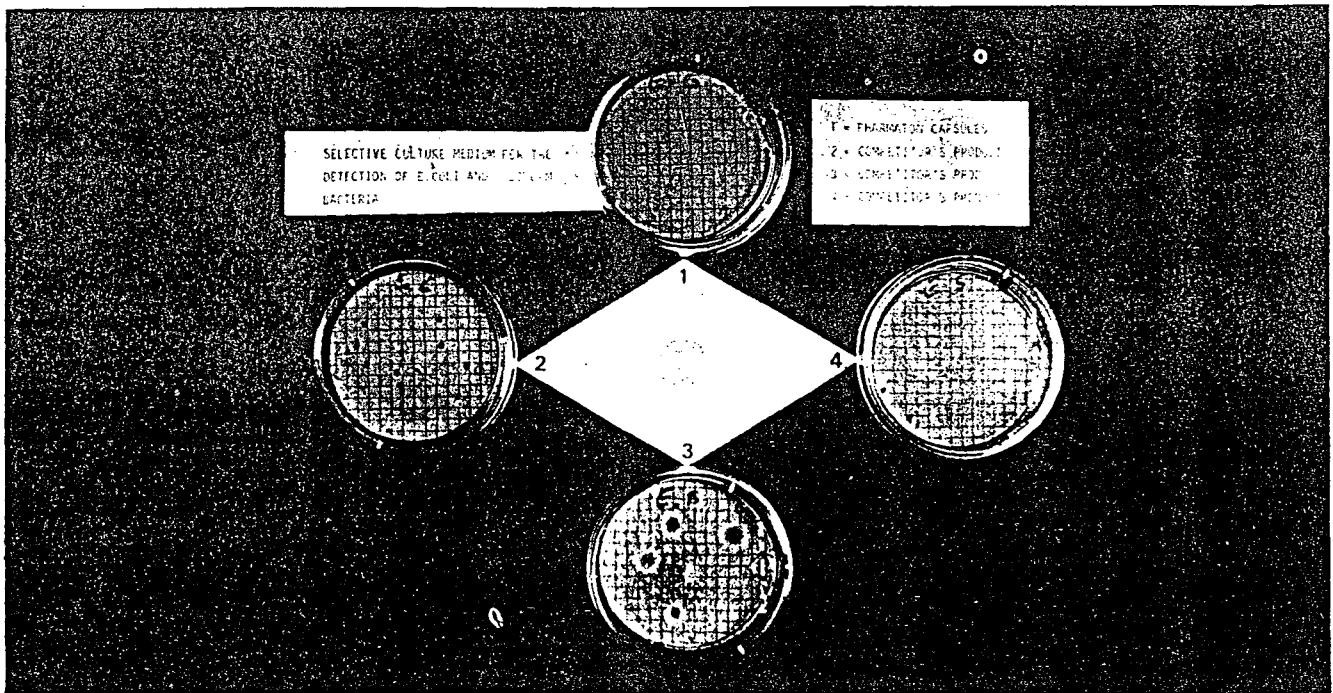


Fig. 12

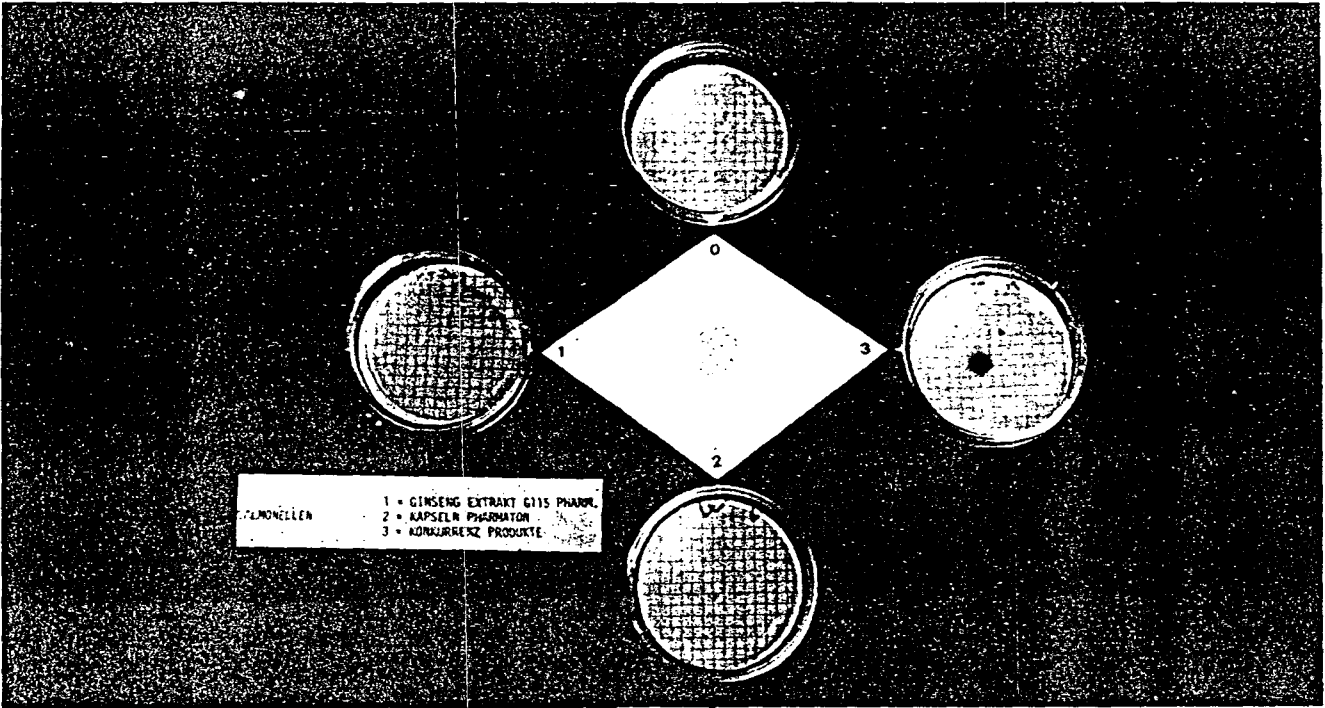


Fig. 13