

### **Introduction**

The inventors are a physician and a microbiologist accomplished in their fields and possessing groundbreaking and unique knowledge of the treatment of hepatitis.

The treatment responsible for the results summarized herein represents years of research and refinement performed directly by the inventors. It is a 'second generation' composition as it builds on the experience gained through extensive clinical testing of the inventors' earlier compositions.

This composition, Treatment A, is the subject of a United States Patent application.

### **Participants**

The participants were 220 men and 40 women primarily from Cairo, Egypt. Participants were, in most cases, paying patients and were referred to the clinic specifically for the treatment of hepatitis C. Mean age at the time of the first visit was 47.81 years (SD 9.12). All patients tested positive via PCR tests before treatments were started. Additionally, 31 patients had a previous history of unsuccessful treatment with interferon, ribavirin or a combination of interferon and ribavirin.

### **Method**

Patients received treatments containing a specific composition of herbal substances. These were administered in the form of orally delivered drops and an orally ingested powder. Dosages were 2 drops delivered twice daily and 3 teaspoons of the herbal powder ingested once daily.

At each monthly visit, patients were thoroughly examined and received enzyme tests (SGPT and SGOT).

**Results**

**PCR Tests**

All patients were PCR positive prior to beginning treatment. After treatment, of 254 patients taking PCR tests (serum and replication), 116 (45.67%) tested negative (table 1.).

**Table 1.**

<b>PCR Results after treatment</b>		
<i>PCR tests taken</i>	254	
<i>positive tests</i>	138	54.33%
<i>negative tests</i>	116	<b>45.67%</b>

Of those patients who had previously received interferon treatment, 38.10% tested PCR negative after the herbal treatment. Although the sample size is quite small, of those patients who were unsuccessfully treated with either ribavirin or a combination of ribavirin and interferon, 1 in 5 (20%) were PCR negative after the herbal treatment. (table 2.)

**Table 2.**

<b>PCR Results and pre-treatments</b>		
	<b>Total</b>	<b>% neg.</b>
<b>Interferon alone</b>	21	<b>38.10%</b>
<b>Ribavirin alone</b>	5	20.00%
<b>Combination treatment</b>	5	20.00%

**Enzyme Tests**

Patient SGPT and SGOT levels were recorded as a ratio of the test result to the test's normal rating. For example, a patient test result of 84 for an SGPT test with a normal rating of 42 would result in a recorded ratio of 2. Using generally accepted practices, a test result was considered within normal range if this ratio did not exceed the value of 2.

Overall, the number of patients with SGPT levels within normal range increased from 56.54% before treatment to 71.15% after the first month of treatment – and increase of 25.85%. The number of patients with SGOT levels within normal range increased

from 57.69% before treatment to 76.06% after the first month of treatment – and increase of 31.84%.

Throughout up to eight months of follow-up visits, SGPT levels remained within normal range for an average of 75.10% of all patients (SD = 2.72%). SGOT levels remained within normal range for an average of 78.55% of all patients (SD = 2.83%).

(table 3.)

**Table 3.**  
**SGPT and SGOT Normalization History**  
 (% with normal results)

	Initial	First Follow-up	Change f/ Initial	Followup Second	Third	Fourth	Fifth	Sixth	Seventh	Eighth	Mean	StDev
<b>SGPT</b>	56.54%	<b>71.15%</b>	<b>25.85%</b>	72.69%	75.29%	76.59%	72.43%	76.32%	78.70%	77.65%	<b>75.10%</b>	<b>2.72%</b>
<b>SGOT</b>	57.69%	<b>76.06%</b>	<b>31.84%</b>	76.65%	79.38%	76.11%	79.75%	79.74%	84.26%	76.47%	<b>78.55%</b>	<b>2.83%</b>

Of the subgroup of patients who, after herbal treatment, tested negative via PCR testing, 59.48% began treatment with SGPT and SGOT levels within normal ranges.

After one month of herbal treatment, an additional 47.74% (for a total of 87.88% of the subgroup) showed normalized SGPT results. Also after one month, an additional 55.07% (for a total of 91.38% of the subgroup) showed normalized SGOT results.

After six months, this same subgroup remained 85.15% normalized for SGPT (down 2.73% from first month) and 86.14% normalized for SGOT (down 6.10%). (table 4.)

**Table 4.**  
**SubGroup - Negative PCR after herbal treatment**

	Normalized Enzyme Tests				
	Initial % Of subgroup	after 1st month		after 6th month	
		additional	Total	Total	change
<b>SGPT</b>	59.48%	<b>47.74%</b>	87.88%	85.15%	<b>-2.73%</b>
<b>SGOT</b>	59.48%	<b>55.07%</b>	92.24%	86.14%	<b>-6.10%</b>

Of the subgroup of patients who, after herbal

treatment, still tested positive via PCR testing, 55.07% began treatment with SGPT and

SGOT level within normal ranges. After one month of treatment, an additional 15.79% (for a total of 63.77% of the subgroup) showed normalized SGPT results. Also after one month, an additional 33.86% (for a total of 73.72% of the subgroup) showed normalized SGOT results.

After six months, this same subgroup remained 68.85% normalized for SGPT (up 5.08% from first month) and 74.38% normalized for SGOT (down 5.33% from first month). (table 5.)

**Table 5.**  
**SubGroup - Positive PCR after herbal treatment**

	Normalized Enzyme Tests				
	Initial % of subgroup	after 1st month		after 6th month	
		additional	Total	Total	change
<b>SGPT</b>	55.07%	<b>15.79%</b>	63.77%	68.85%	<b>+5.08%</b>
<b>SGOT</b>	55.07%	<b>33.86%</b>	73.72%	74.38%	<b>+0.66%</b>

### Discussion

PCR testing confirms a high level of effectiveness against hepatitis C as indicated by the negative test results achieved in 45.67% of patients after treatment with the herbal compositions. Of significant note, a 38.10% effectiveness was also achieved with patients who had previously been unsuccessfully treated with interferon.

Enzyme levels as measured through SGPT and SGOT tests were substantially normalized after just the first month of treatment. The results show a 25.85% increase in the number of patients with normal SGPT levels and a 31.84% increase in the number of patients with normal SGOT levels. These dramatic, one-month results were maintained throughout 8 and more months of follow-ups, with a standard deviation of less than 3% (SD=2.72% for SGPT and 2.83% for SGOT, respectively).

In the subgroup of patients who ultimately would test negative via PCR, an additional 47.74% were normalized for SGPT levels and 55.88% for SGOT levels – this again, after one month of treatment. After six months, these improvements were substantially maintained with only a 2.73% and 6.10% decrease in total normalized numbers for SGPT and SGOT, respectively.

For the subgroup of patients who ultimately would still test positive via PCR, enzyme levels were nonetheless dramatically improved. After one month, an additional 15.79% of patients tested normal for SGPT levels. SGOT levels were normalized in an additional 33.86% of the patients. After six months these improvements not only held but even increased slightly, by 5.08% for SGPT levels and 0.66% for SGOT levels.

Importantly, these results were achieved with minimal, adverse side effects. Even more, it may be suggested that the treatment is associated with an overall improvement in the general conditions associated with hepatitis C. In cases where reversals could not be achieved as measured through PCR or enzyme testing, a large majority of patients still showed substantial symptom reduction and reported improved feelings of strength and well-being.