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**A SCIENTIFIC EVALUATION OF HIRANYAPRAASH™ AN AYURVEDIC NANOMEDICINE AS ANTURAL IMMUNE BOOSTER IN CHILDREN**

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**ABSTRACT**

*In the present day protecting child from endless germs and viruses is the need of hour. Some pediatricians consider in a year six to seven bouts of flu or ear infections in children are normal. But there are healthy habits by which the child's immunity can be boosted and reduction in episodes of illness can be achieved. Adequate sleep, nutrition, regular exercise, hygiene maintenance, being away from allergens and germs are the good practices which can reduce the morbidity and boost the immune system. One such practice is Swarna Prashana explained in ancient literatures of Ayurveda which enhances the healthy status of child. Hiranya Praash™ is a patented, research product designed and developed by Dr. Krishna Life Science Ltd., Manipal. It is safe, natural rejuvenative with the power of gold. Pure gold is processed with selected organic, bio-active herbs by using patented techniques. Material and Methods: An assessment of Cell mediated immune function by delayed type hypersensitivity (DTH) test. Survey was carried out in various centres related the institution and hospital. 104 children randomly assessed for clinical study. 2 drops of Hiranya prash™ administered to the children below the age group of 5 years and 4 drops administered above the age group of 5 years. The survey and clinical assessment was done and data obtained was analyzed statistically. Conclusion: Study has proved immune stimulant activity of Hiranyapraash. It is found to be Hiranyapraash™ is beneficial in preventing the respiratory manifestations and beneficial in increasing the appetite of children. Analysis of data on behavioural assessments shows high statistical significance in parameter school work performance and subject understanding ability. Key words: Hiranyapraash™, Swarna Prashana, Ayurveda, Immunity*



## INTRODUCTION:

In the present day protecting child from endless germs and viruses is the need of hour. Some paediatricians consider in a year six to seven bouts of flu or ear infections in children are normal. But there are healthy habits by which the child's immunity can be boosted and reduction in episodes of illness can be achieved. Adequate sleep, nutrition, regular exercise, hygiene maintenance, being away from allergens and germs are the good practices which can reduce the morbidity and boost the immune system.

One such practice is *Swarna Prashana* explained in ancient literatures of *Ayurveda* which enhances the healthy status of child. *Swana Prashana* literally means administration of gold. Pure gold possesses the special properties of balancing the *Doshas* of body and mind thereby maintaining total health. It is known to improve the intellect, wisdom, grasping power and memory. It has the ability to improve natural immunity and prevent the diseases. Nano particles of gold are rejuvenative.

Administration of gold to infants has been under practice traditionally in India since thousands of years and the references are available not only in *Ayurveda* but also in other ancient texts of Indian wisdom.

Various formulations, duration of administration and benefits of

*Swarnayogas (formulations of gold)* have been explained in classical texts of *Ayurveda*. *Sushruta*<sup>1</sup> and *Vagbhata*<sup>2</sup> have prescribed gold with various drugs to the new born child immediately after the birth. Both *Sushruta* and *Vagbhata* have mentioned about four gold preparations for prolonged use<sup>3,4</sup>. According to *Sushruta*, one year of daily administration of gold preparation is helpful in enhancing the *medha (intelligence)*, *ayushya (longevity)*, *arogya (health)* and *pushti (Opulence)*<sup>5</sup>. *Kasyapa* has explained about the method of *Swarna Prashana*, administration mode, *anupana (vehicle)*, duration of administration and benefits<sup>6</sup>. *Swarna Prashana* boosts immune system and prevents the various infections. It enhances the intellectual powers and memory. *Charaka Samhita* has advised use of gold immediately after birth to the new born along with honey and ghee<sup>7</sup>.

*Swarna Prashana* is being practiced by various institutions and *Ayurveda* Paediatricians successfully. *Hiranyaprash*<sup>TM</sup> the patent medicine of Dr. Krishna Life Sciences Ltd, Manipal, a GMP certified unit, is found effective in clinical practice in enhancing immune system by preventing respiratory illnesses, gastro intestinal disorders and developmental problems. So the Institution took initiative to do survey and clinical study and the data was documented. Analysis was done to assess the efficacy on various parameters.

## MATERIALS AND METHODS

### Drug:

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*Hiranyaprash*<sup>TM</sup> is a specialized research product designed and developed by Dr. Krishna Life Sciences Ltd, Manipal. Here pure gold is processed with the help of various medicinal plants by a patented *Dravyashudh*<sup>TM</sup> technique. *Hiranya Praash*<sup>TM</sup> is a unique bioactive micro-nano emulsion containing gold particles and herbal ingredients to form biological nano complexes of gold. Processed Swarna Bhasma is divided in this specially harvested honey with continuous levgation to get mico-nano emulsion

### **Safety:**

The toxicity study (CEFT#3999/08) conducted in Sri Ramachandra Institute Chennai has established the safety of the drug. The test substance *Hiranyaprash*<sup>TM</sup> falls in Category- 5 in the Globally Harmonised System (GHS), the hazard category defined by:  $2000\text{mg/kg} < \text{LD}_{50} < 5000\text{mg/kg}$ .

### **Experimental study:**

The animal experimentation conducted in Sri Ramachandra Institute Chennai to see immunostimulant property (CEFT#1009/10) found to possess the potent immunostimulatory effect on male Swiss albino mice when administered at the dose level of 50mg/kg b.wt.

### **Clinical Study:**

Randomly 104 children were selected for the clinical observation from the population those who are taking *Hiranyaprash*<sup>TM</sup>. Around 6000 to 8000 children are administered *Hiranyaprash*<sup>TM</sup> every month in Muniyal institute of Ayurveda Medical

Sciences and Hospital, Manipal, various centres, hospitals and clinics.

### **Aim and objective of the study:**

To see the efficacy of *Hiranyaprash*<sup>TM</sup> in preventing disorder in children.

To see efficacy of *Hiranyaprash*<sup>TM</sup> in reducing the disease frequency in children.

### **Source for study:**

Out Patient Department of *Kaumarabhritya* (Ayurvedic paediatrics), Muniyal Ayurveda Hospital and Research Institute, Manipal.

Muniyal Ayurveda Family clinics.

### **Sample Size:**

104 children undergoing *Hiranyaprash*<sup>TM</sup> were included in the study.

### **Design of Study: Single group**

Drug: *Hiranyaprash*<sup>TM</sup> is the patent drug of Muniyal Pharmacy, Manipal of 20 ml packing.

Dose of *Hiranyaprash*<sup>TM</sup>: 2drops for age below 5years and 4drops for age above 5years.

### **METHODOLOGY:**

The survey proforma was given to the parents for providing the information. Proforma had question in the Kannada language which had questions related to many aspects of the drug, administration, taste, observed changes, school performances and their opinion. Questions were framed to get the data related to information before *Hiranyaprash*<sup>TM</sup>

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administration and after administration. The parents were asked to fill forms of survey proforma and submitted to the concerned centre. Then the data was collected and put in the master chart for analysis.

Inclusion criteria:

Children who have undergone 6 consecutive *Hiranyaprash*<sup>TM</sup>

Children who have taken only *Hiranyaprash*<sup>TM</sup>.

Children under the age of 16 years.

Exclusion criteria:

Children who have not been administered 6 doses of *Hiranyaprash*<sup>TM</sup>

Children who have administered other than *Hiranyaprash*<sup>TM</sup> for *Swarna Prashana*.

Children who lapse the dose of *Hiranyaprash*<sup>TM</sup>.

Assessment criteria:

Following manifestations are observed for assessments-

Respiratory system

Common cold

Sneezing

Cough

Breathing difficulty

Head ache

Fever

Gastro Intestinal System

Loss of appetite

Distension of abdomen

Vomiting

Loose stools

Hard stools

Abdominal pain

Mucus with stools

Developmental problems

All these 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> criteria were graded under the following uniform scoring pattern.

Always -4

Frequently- 3

Occasionally- 2

Not Present- 1

Absent- 0

Scholastic work performances.

Behavioural Adjustments with classmates.

Behavioural Adjustments with teachers.

Behavioural Adjustments with parents.

Subject understanding ability.

All these 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup> and 8<sup>th</sup> criteria were graded under the following uniform scoring pattern.

Poor- 01

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Moderate- 02

Excellent- 03

The data are put in the master chart which has all information of 104 children and analysed statistically using various tests

### OBSERVATIONS

Following observations are found from 104 children undergone *Hiranyaprash*<sup>TM</sup>.

58 (55.77%) children were below the age of 5 years and 46 (44.23%) children were above 5 years of age. Sex ratio showed male children were 55 (52.88%) and female children were 49 (47.12%) in number. In majority cases i.e, 63 (60.58%) cases it was observed that mother was the informant.

80 (76.92%) children mentioned the *Hiranyaprash*<sup>TM</sup> is sweeter in taste. This indicates the palatability of the drug. The drug had no refusal for administration in 103 (99.04%) children. 59 (56.73%) children were school going children.

Table No. 1: Showing Age groups of children in the study.

Sl. No.	Age	No. of children	%
1	Below 5years	58	55.77
2	Above 5years	46	44.23

Graph No. 1: Showing Age groups of children in the study.

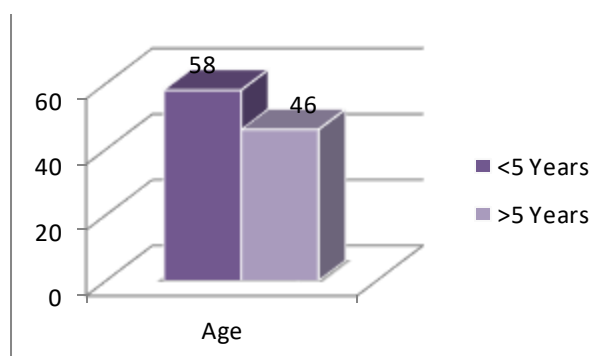


Table No. 2: Showing sex ratio.

Sl. No.	Sex	No. of children	%
1	Male	55	52.88
2	Female	49	47.12

Graph No. 2: Showing sex ratio.

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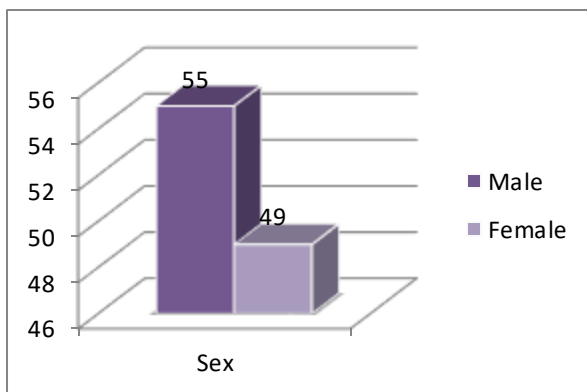


Table No. 3: Showing percentage of Informant who filled the survey forms of Hiranyaprash™ clinical survey.

Sl. No.	Informant	Number	%
1	Father	37	35.58
2	Mother	63	60.58
3	Sister	2	01.92
4	Aunt	2	01.92

Graph No. 3: Showing percentage of Informant who filled the survey forms of Hiranyaprash™ clinical survey.

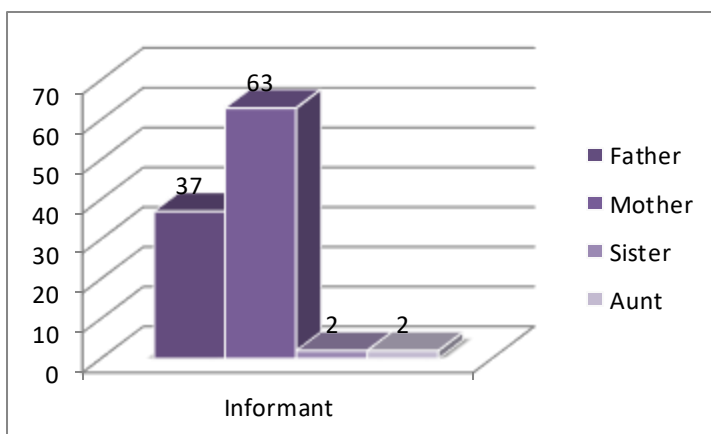


Table No. 4: Showing the taste of Hiranyaprash™ as stated by the Child.

Sl. No.	Taste	No. of children	%
1	Sweet	80	76.92
2	Bitter	1	00.96
3	Not Mentioned	23	22.12



Graph No. 4: Showing the taste of Hiranyaprash™ as stated by the Child.

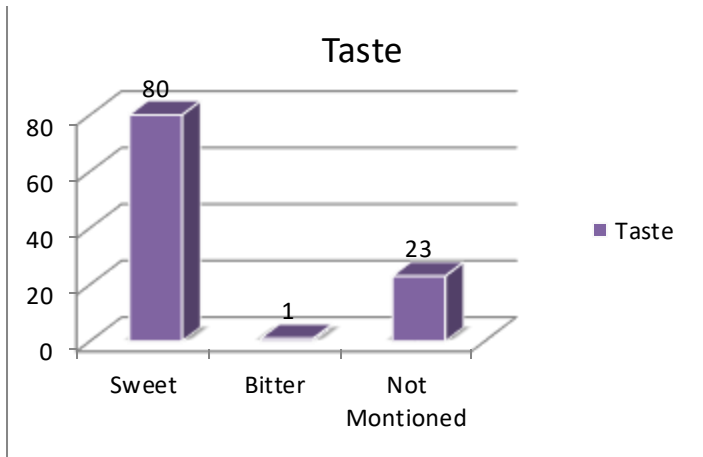


Table No. 5: Showing the refusal for Hiranyaprash™ administration.

Sl. No.	Refusal	Number	%
1	Yes	1	00.96
2	No	103	99.04

Graph No. 5: Showing the refusal for Hiranyaprash™ administration.

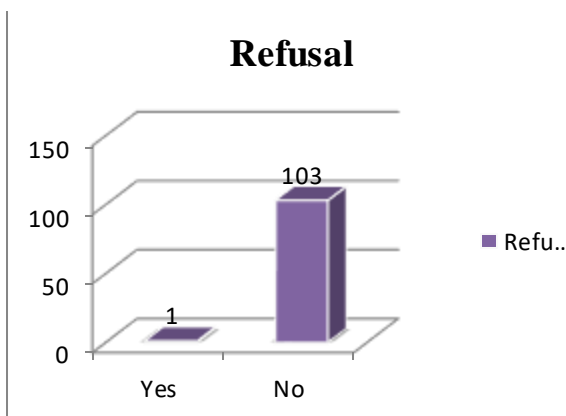


Table No. 6: Showing the no. of children school going or not.

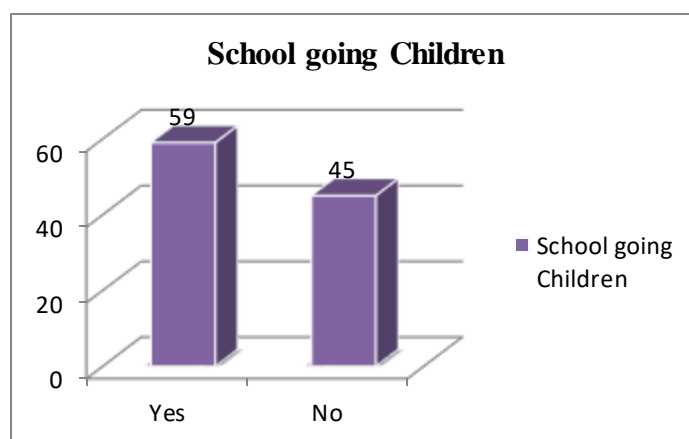
Sl. No.	School going	Number	%
1	Yes	59	56.73





2	No	45	43.27
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Graph No. 6: Showing the no. of children school going or not.



## RESULTS

In the study 104 children's data was analyzed statistically and following results were obtained. Data Before administration of *Hiranyaprash*<sup>TM</sup> and the data obtained from the clinical survey are analyzed by applying paired t tests on different parameters of respiratory system, GIT and behavioural parameters.

Table No. 7: Showing the analysis of data on Respiratory system manifestations.

Sl. No.	Parameter	n	Mean	SD	SE	't' Value	df	P Value
1	Cold	87	0.7701	1.0081	1.1081	7.125	86	<0.001
2	Sneezing	58	0.7586	1.0141	0.1332	5.697	57	<0.001
3	Head ache	43	0.3488	0.6504	0.0992	3.517	42	<0.001
4	Cough	77	0.7922	1.0555	0.1203	6.586	76	<0.001
5	Dyspnoea	41	0.4390	0.8381	0.1309	3.354	40	<0.001
6	Fever	69	0.8116	0.9436	0.1136	7.144	68	<0.001

Analysis of data on Respiratory system manifestations shows high statistical significance for all parameters- cold, sneezing, head ache, cough, dyspnoea and fever.

Table No. 8: Showing the analysis of no. of children with respiratory symptoms.

Sl. No.	Parameter	No. of children having symptoms	
		Before administration of <i>Hiranyaprash</i> <sup>TM</sup>	On the Date of Survey
1	Cold	87	73
2	Sneezing	58	50

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3	Head ache	43	38
4	Cough	77	66
5	Dyspnoea	41	36
6	Fever	69	55

Table shows reduction in the occurrence of respiratory manifestations by the administration of *Hiranyaprash*<sup>TM</sup>.

Table No. 9: Showing of analysis of data on GIT manifestations.

Sl. No.	Parameter	n	Mean	SD	SE	't' Value	df	P Value
1	Loss of appetite	75	0.4267	1.0157	0.1173	3.638	74	<0.001
2	Distension of abdomen	42	0.2857	0.8050	0.1242	2.300	41	<0.05
3	Abdominal pain	54	0.4444	1.1438	0.1556	2.855	53	<0.01
4	Vomiting	47	0.1702	0.8423	0.1229	1.385	46	>0.05
5	Hard stools	43	0.1163	0.6252	0.0953	1.220	42	>0.1
6	Loose stools	43	0.1163	0.5859	0.0894	1.301	42	>0.1
7	Mucus with stools	43	0.2558	0.8478	0.1293	1.979	42	>0.05

Analysis of data on GIT manifestations shows high statistical significance in the parameter loss of appetite; moderate significance in the parameters distension of abdomen and abdominal pain; statistical insignificance in parameters vomiting, hard stools, loose stools, mucus with stools.

Table No. 10: Showing the analysis of no. of children with GIT symptoms.

Sl. No.	Parameter	No. of children	
		Before administration of <i>Hiranyaprash</i> <sup>TM</sup>	On the Date Survey
1	Loss of appetite	75	66
2	Distension of abdomen	42	36
3	Abdominal pain	54	46
4	Vomiting	47	42
5	Hard stools	43	40
6	Loose stools	43	38
7	Mucus with stools	43	39

Table shows reduction in the occurrence of GIT manifestations by the administration of *Hiranyaprash*<sup>TM</sup>



Table No. 11: Showing the analysis of data on behavioral assessments.

Sl. No.	Parameter	n	Mean	SD	SE	't' Value	df	P Value
1	School work performances	56	0.1786	0.4309	0.0576	3.101	55	<0.005
2	Behavioural adjustments with classmates	56	0.1071	0.3121	0.0417	2.569	55	<0.02
3	Behavioural adjustments with teacher	56	0.071	0.3223	0.0431	1.658	55	>0.1
4	Behavioural adjustments with parents	56	0.018	0.3010	0.0402	0.444	55	>0.1
5	Subject understanding ability	56	0.1786	0.3865	0.0516	3.458	55	<0.001

Analysis of data on behavioral assessments shows high statistical significance in parameter school work performance and subject understanding ability, Moderate significance in the parameter behavioral adjustments with classmates, statistical insignificance in the parameters behavioral adjustment with teacher and parents.

## DISCUSSION

Effect of Swarna bhasma and Gold preparations:

*Swarna bhasma* is time tested in Indian system of Medicine with a praiseworthy therapeutic efficacy. Even the utensils of gold were also in practice in ancient times with the view of prevention of disease. Now it has been established that Swarna bhasma is of Nano particle size and remains mostly in the form of mono atomic gold<sup>8</sup>.

The Swarna bhasma and gold preparations are established as having efficacy as nootropic activity<sup>9</sup>. The *Swarna bhasma* has been scientifically found effective as free - radical scavenging activity<sup>10</sup> inflammatory diseases, asthma, respiratory illnesses and immunological disorders<sup>11, 12, 13</sup>.

Numbers of its properties were mentioned in the classical texts of Ayurveda like rejunavator, aphrodisiac, memory booster etc<sup>14</sup>. It is used in numerous disorders like *Grahani* (sprue), *Pandu* (anemia), *Asthikshaya* (osteoporosis), *Jirna Vyadhi* (chronic disorders) etc<sup>15</sup>. It is chief ingredient in therapeutically potent medicines like *Makaradhwaja*, *Swarna Malini Vasanata*, *Vasantakusumakara Rasa*. Its few therapeutic properties like analgesic<sup>16</sup> anticataleptic, anti-anxiety and antidepressant<sup>17</sup>, activity antioxidant<sup>18</sup> and augmenting effect<sup>19</sup> were screened earlier. Its role on a normozoospermia,<sup>20</sup> male infertility<sup>21</sup> and oligoazospermia<sup>22</sup> was found to have significant results also specific quantity of gold was observed in semen of healthy fertile men<sup>23,24</sup>. Recent studies of gold nanoparticles were found effective for antiangiogenic and anti-cancer property<sup>25</sup>. *Swarna Bhasma* is used as a chief ingredient in *Hiranya praash*<sup>TM</sup> for

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neonates and children. Unlike traditional method of preparation of Swarna Bhasma, here the prepared drug is further processed in selected herbs (specified in SOP) to infuse special immunomodulatory, memory boosting properties in the product. Unique feature of this product is utilization of specially harvested honey with medicinal properties. Honey is harvested by bee keeping in gardens containing selected plants whose flowers are known to have anticancerous, immunomodulatory antimicrobial and antioxidant properties. Honey has been reported to have an inhibitory effect on around 60 species of bacteria, some species of fungi and viruses. Antioxidant capacity of honey is important in many disease conditions and is due to a wide range of compounds including phenolics, peptides, organic acids, enzymes, and Maillard reaction products. This honey contains flavonoides (such as apigenin, pinocembrin, kaempferol, quercetin, galangin, chrysin and hesperetin), phenolic acids (such as ellagic, caffeic, p-coumaric and ferulic acids), ascorbic acid, tocopherols, catalase (CAT), superoxide dismutase (SOD), reduced glutathione (GSH), Millard reaction products and peptides. Most of those compound works together to provide a synergistic antioxidant effect. Honey an essential ingredient of *Hiranyapraash*<sup>TM</sup> has been reported to be as an anti-microbial agent<sup>26</sup>, effective in gastrointestinal disorders, in healing of wounds and burns, and to provide gastric protection against acute and chronic gastric lesions<sup>27</sup>. Honey used as a vehicle here is described as *Yogavahi* in Ayurveda. It acts as a

bioenhancer. This further helped in enhancing the efficacy of *Hiranyapraash*<sup>TM</sup>

Effect of *Hiranyapraash*<sup>TM</sup>:

The drug *Hiranyapraash*<sup>TM</sup> is found safe and immunostimulant by the experimental studies carried out in Sri Ramachandra Institute, Chennai.

Analysis of data on Respiratory system manifestations shows high statistical significance for all parameters- cold, sneezing, head ache, cough, dyspnoea and fever. *Hiranyapraash*<sup>TM</sup> is very much beneficial in reducing the symptoms of respiratory manifestations. *Hiranyapraash*<sup>TM</sup> is beneficial in preventing the respiratory manifestations, hence it can be concluded that *Hiranyapraash*<sup>TM</sup> increases the immunity of the child. This is due to action of Gold in enhancing the nonspecific immunity and action over the inflammation of respiratory system mucosa.

Analysis of data on GIT manifestations shows high statistical significance in the parameter loss of appetite; moderate significance in the parameters distension of abdomen and abdominal pain; statistical insignificance in parameters vomiting, hard stools, loose stools, mucus with stools. *Hiranyapraash*<sup>TM</sup> is beneficial in increasing the appetite of children.

Analysis of data on behavioural assessments shows high statistical significance in parameter school work performance and subject understanding ability, Moderate significance in the parameter behavioural adjustments with classmates, statistical insignificance in the

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parameters behavioural adjustment with teacher and parents. *Hiranyaprash*<sup>TM</sup> is beneficial in increasing the intelligence; thinking ability, subject understanding ability. *Hiranyaprash*<sup>TM</sup> acts as *Medhya Rasayana*. The *Swarna bhasma* has the nootropic property by which the cognitive and behavioural functions are found with significant changes.

### CONCLUSION

*Hiranyaprash*<sup>TM</sup> is beneficial in enhancement of physical and mental health of children. It is found that the drug is beneficial in enhancing the immunity of the child. The drug found safe to use. The results found significant in the prevention and control of respiratory, GIT, and behavioural parameters. Further studies are required in the analysis of effect on IQ, Immunological status and different disorders of children.

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