2.1 GREEN TEA

Investigations

Frei et al. performed a considerable number of human involvement studies. A significant raise in human plasma antioxidant capacity was demonstrated after utilization of moderate amounts of green tea. i.e. 1-6 cups/day.27

Klaunig et al. performed a study on 40 male smokers plus 27 men and women i.e., smokers and non smokers in the United States. The volunteers were asked to take around 6 cups per day of green tea for seven days. Free radical generation and lipid peroxidation were reduced drastically.27

Erba et al. suggest the ability of green tea, protects against oxidative damage in humans by improving overall antioxidative status. Numerous clinical, In-vitro studies using cancer lines and animals have shown that, oral, esophagus, stomach, skin, lung, liver, prostate, kidney, and other organ cancers were inhibited by green tea.27

Rosengren indicated that the green tea catechins decrease breast tumor growth in rodents, by reducing the proliferation of breast cancer cells In-vitro. In-vitro studies have confirmed that “Tamoxifen works synergistically with EGCG. This combination is cytotoxic to breast cancer cells. Catechins have shown significant potential in the treatment of breast cancer.27
Mittal et al. found that green tea inhibits telomerase activity by 40 to 55 percentages. Telomerase is elevated in greater than 90 percentages of breast carcinomas and as a result has received much notice as a target for breast cancer therapy and cancer diagnostic research.27

Wu et al. reported a relation between green tea and breast cancer. He selected only women volunteers for this study. He compared the risk of breast cancer in regular green tea drinkers and non drinkers. There is an inverse relation between drinkers and non drinkers. i.e., as increasing the amount of green tea intake, decreases risk of breast cancer, especially in its early stages. These studies are resulted in Japanese women, who diagnosed with breast cancer.27

Zhou et al. reports that, Asian women (who took green tea and soy products in their diet regularly), who less common development of breast cancer. They concluded the green tea and dietary soy phytochemical concentrate acts as a potential effective dietary regimen for inhibiting progression of estrogen dependent breast cancer.27

Zhang et al. worked on green tea and ovarian risk in women. He reported that, escalating frequency and duration of green tea consumption declines ovarian cancer risk. In the same line of explore, Yu et al. reported that EGCG inhibits the growth of prostate cancer adenoma cells and further, it induces the apoptosis of same.27

Jian et al. conducted a case control study in China that concludes, increasing frequency, duration and quantity of green tea consumption
reducing the prostate cancer risk. The dose response relationships were also noteworthy, suggesting that green tea is protective against prostate cancer.  

Yamamoto et al. reported that GTP can enhance the effectiveness of chemo/radiation therapy to promote cancer cell death while protecting normal cells. Epidemiological studies, on the one hand, have suggested that green tea high consumption protects against the development of chronic active gastritis and hampers the risk of stomach cancer; in addition, the green tea intake protects the intestinal mucosa against atrophy, if consume before fasting.  

Yang et al. concluded that habit of consuming the moderate amounts of green or oolong tea, 120 ml per day or more for 1 year appreciably reduces the risk of developing hypertension in the population of China. Hodgson et al. stated that the long term regular drinking of green tea may have a constructive effect on blood pressure in older women.  

Nakachi et al. concluded that decreased relative risk of death from cardiovascular disease in men and in women on consuming ≥ 10 cups per day. Yokozawa et al. reported that, LDL cholesterol oxidation and elevated serum antioxidative activity can be achieved by the administration of GTP.
Table 2.1 Results Generated from Epidemiological Studies of Green Tea

<table>
<thead>
<tr>
<th>Investigator &amp; year</th>
<th>Country</th>
<th>Type of study/subject</th>
<th>Green tea consumption</th>
<th>Health effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breast Cancer</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Inoue et al. 2001.</td>
<td>Japan</td>
<td>Prospective study, 1160 females, Invasive breast cancer, Mean age = 51.5 years</td>
<td>≥6 cups/day 3-5 cups/day 0-2 cups/day</td>
<td>A decrease of the risk of cancer recurrence is observed (especially in early stage cancer stage) with a consumption of ≥3 cups/day.</td>
</tr>
<tr>
<td>Wu et al. 2003.</td>
<td>USA</td>
<td>Case control study, Asian American women, 501 breast cancer patients, 594 controls.</td>
<td>&gt;85.7 ml/day, 0-85.7 ml/day, No drinkers</td>
<td>There is a significant trend of decreasing risk of breast cancer with increasing amount of tea intake respectively, in association with no. 0-85 ml/day and &gt;85.7 ml/day.</td>
</tr>
<tr>
<td><strong>Ovarian Cancer</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Zhang et al. 2002.</td>
<td>China</td>
<td>Case control study 254 ovarian cancer patients and 652 controls.</td>
<td>Validated questionnaire</td>
<td>Increasing frequency and duration of tea drinking can reduce the risk of ovarian cancer compared with non drinkers.</td>
</tr>
<tr>
<td><strong>Prostate Cancer</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Jian et al. 2004.</td>
<td>China</td>
<td>Case control study 130 prostate adeno carcinoma patients and 274 controls.</td>
<td>Face to face interview using a structured questionnaire</td>
<td>The prostate cancer risk declined with increasing frequency, duration, and quantity of green tea consumption for those consuming more than 1.5 kg of tea leaves yearly.</td>
</tr>
</tbody>
</table>
Table 2.1 (Cont...)

<table>
<thead>
<tr>
<th>Investigator &amp; year</th>
<th>Country</th>
<th>Type of study/subject</th>
<th>Green tea consumption</th>
<th>Health effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal Cancer</strong></td>
<td></td>
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</tr>
<tr>
<td>Huang et al. 1999.</td>
<td>Japan</td>
<td>Case control study, 887 gastric cancer, 28619 control, Age 20-79 y.</td>
<td>6 cups/day, 3-5 cups/day, 1-2 cups/day, Never.</td>
<td>Consumption of more than 6 cups/day vs. never drinking decreased the risk of gastric cancer.</td>
</tr>
<tr>
<td>Shibata et al. 2000.</td>
<td>Japan</td>
<td>Cross sectional study, 636 men and women, mean age: Men-59.2y &amp; Women-60.4 y</td>
<td>≥10 cups/day, 0-9 cups/day.</td>
<td>Consumption of more than 10 cups/day reduces the risk of chronic atrophic gastritis.</td>
</tr>
<tr>
<td>Nakachi et al. 2000.</td>
<td>Japan</td>
<td>Prospective cohort study, 8552 adults.</td>
<td>≥10 cups/day, 4-9 cups/day, &lt;3 cups/day.</td>
<td>Consumption of more than 10 cups/day decrease the risk of stomach cancer and colorectal cancer.</td>
</tr>
<tr>
<td>Setiawan et al. 2001.</td>
<td>China</td>
<td>Case control study, 166 Chronic atrophic gastritis, 133 gastric cancers, 433 controls.</td>
<td>21 cups/week, 1-21 cups/week, Never.</td>
<td>Significant inverse association between tea drinking and gastric cancer or chronic atrophic gastritis.</td>
</tr>
<tr>
<td>Zhong et al. 2001.</td>
<td>China</td>
<td>Case control study, Only women, 649 lung cancer cases, 675 controls women.</td>
<td>Face to Face interviews.</td>
<td>Among non smoking women, consumption of green tea was associated with a reduced risk of lung cancer, and the risks decreased with increasing consumption.</td>
</tr>
</tbody>
</table>
Katiyar et al. reported that, either chemical or UV radiation induced skin cancers were inhibited in laboratory animal models up on the oral consumption of GTP or its topical application. Topical treatment of EGCG or GTP and oral consumption of GTP results in prevention of UVB induced inflammatory responses, oxidative stress and immune suppression which are the biomarkers for several skin disease conditions. GTP and EGCG topical application in laboratory animals, prior to exposure to UVB protects local as well as systemic immune suppression. The In-vivo animal and human studies have suggested that GTP are photo protective in nature, and can be used as pharmacological agents for the prevention of solar UVB light induced skin disorders as well as photo aging, melanoma and non melanoma skin cancers.\(^\text{27}\)

Hirano et al. and Ohmori et al. have worked to find a relation between green tea and myocardial infarction. Through seven studies, increase in green tea consumption of three cups per day, incidence rate of myocardial infarction can estimate to decrease by 11%. In addition an inverse association of green tea intake and myocardial infarction has found.\(^\text{27}\)

Raederstorff et al. were fed a high cholesterol and high ft diet in rats. They studied the mode of action of EGCG on various parameters. Drastically reduced cholesterol and LDL cholesterol were observed in the group fed 1% EGCG when compared to the non treatment group. EGCG
decreases cholesterol absorption in the digestive tract by interfering with the micellar solubilization of cholesterol.\textsuperscript{27}

Dulloo et al. reported thermogenic properties of green tea extract which is rich in catechins. He concluded that green tea has thermogenic properties and promotes fat oxidation beyond than those explained by its caffeine content the green tea extract may play a role in the control of body composition via sympathetic activation of thermogenesis, fat oxidation, or both. The same investigator indicated that the thermogenic properties of green tea could exist primarily in an interaction between its high content in catechins and the presence of caffeine with sympathetically released noradrenaline.\textsuperscript{27}

Wu et al. conducted a study on individuals who have practice of tea consumption more than ten years. He studied and concluded a inverse relationship between fat distribution / fat percentage and consumption of green tea.\textsuperscript{27}

Wu et al. studied a complicated relationship among insulin sensitivity, glucose tolerance and green tea supplementation. Rats were randomly grouped into control and test. Standard diet and deionized distilled water was fed to control groups. A green tea solution (500 mg of green tea diluted to 100 ml of de ionized distilled water) and standard diet was fed to test group. After 12 weeks study, the test group shows lower fasting plasma glucose levels, insulin, triglycerides and free fatty acids than that of control rats.\textsuperscript{27}
Takabayashi et al. and Yee et al. proved that Helicobacter pylori infection can be effectively inhibited by green tea catechins. Further green tea does not show any effect over intestinal flora and definitely this will be an immense benefit against other antiseptic agents. Initial stages of influenza virus and herpes simplex virus can be effectively treated by green tea.

Weber et al. observed that adenovirus infection is inhibited *in-vitro* by green tea catechins. Hirasawa and Takada indicated the antifungal activity of green tea catechins against Candida albicans, and the convenience of a combined treatment with catechins and lower doses of anti mycotics; this treatment may help to avoid the side effects of antimycotics.\(^\text{27}\)

Gupta et al. reported that green tea protects lens of eye, by preserving the anti oxidant system of eye. Skrzydlewska et al. indicated a beneficial effect of green tea in alcohol intoxication. Along with the above properties, which helped to the detection of green tea as functional food by some authors, it is not to forget its current use in the preparation of a variety of food, pharmaceutical preparations, dentifrices and cosmetics. This added use is essentially due to its antioxidant activity, which makes it a natural, efficient and safe preservative.\(^\text{27}\)

Imai et al. and Nakachi et al. conducted a study surveyed 8552 peoples, having age above 40 years, on consumption of green tea and also on their life style. During the 10 years of study, it was found a total
of 419 cancer patients, 244 males and 175 females, among participants in the cohort study, and then divided their daily green tea consumption into three groups; under three cups, 120 ml/cup, 4-9 cups and over 10 cups per day. The average age at cancer onset of all these patients from clinical documents was calculated. The results shows that cancer onset for patients who had consumed over 10 cups of green tea per day was 7.3 years later among females, and 3.2 years later among males, than those of patients who had consumed less than three cups per day. Since most of the male patients who had consumed over 10 cups per day were current smokers, higher tobacco consumption was probably the main reason for the difference in delayed cancer onset between females and males. This was the first evidence from a cohort study that drinking green tea prevents cancer in humans. When the cancer preventive effects of green tea was next analyzed by organs, patients who had consumed over ten cups per day, showed lesser relative risk of all organ cancers, including lung, colorectal, liver and stomach.42

Johnson et al. used cell culture models to study the effect of EGCG on cancer. He reported that prostate cancer cell line apoptosis was promoted by green tea and thus cell viability was decreased. Further there is no effect on non cancerous cell lines. He administered standardized green tea polyphenols to the animal models by adding the same in drinking water. He observed that, all the animals get delay in the development and progression of prostate cancer. They conducted 3
clinical trials in prostate cancer patients and suggest that green tea acts as chemopreventive agent and its role is distinctive.\textsuperscript{43}

A study took a group of students aged 19-37 years to analyze the short term consumption of green tea. Volunteers were instructed to take green tea for only 14 days, at the rate of 4 cups per day, and not to alter their food habits. The results showed that short term consumption of commercial green tea reduces systolic and diastolic blood pressure, fasting total cholesterol, and body fat and body weight. These reductions were significantly observed in overweight people. Hence green tea decreases the risk of CVD even in obese people. In a study made by Israel Institute of Technology, concluded that green tea prevents the drying and rescuing of already damaged neurons in the brain and hence it can be used against Parkinson’s and Alzheimer’s diseases in the old age.\textsuperscript{44}

At the National institute of Chemistry in Ljubljana, Slovenia, a study was performed and reported the antimicrobial property of green tea. EGCG binds with ATP binding site of a bacterial enzyme \textit{gyrase} and thus inhibits the same. Hence green tea can used to maintain in oral hygiene.\textsuperscript{45} Green tea with mushrooms able to cut 90\% of breast cancer occurrences. This report is made from a case control study in 2,018 women.\textsuperscript{45,46} Green tea is very good for eye. Lens, retina and other parts of eye absorbs green tea catechins. This is a result of a study conducted at Hong Kong University on rats. Further this research in the same area
concluded that green tea prevents many eye diseases including glaucoma. The absorbed catechins in the eye able to reduce oxidative stress more than 20 hours.\textsuperscript{45,47}

Tohoku University, Japan, selected 40,530 Japanese adults, having age range 40–79 years. The selected individuals do not have any history of stroke, heart diseases or cancer. There is 16\% reduction in all cause mortality, in those who consumed 5 or more cups of tea per day. And 26\% reduction in risk of CVD who consumed less than one cup per day. Green tea increases life span by protecting CV system of the body.\textsuperscript{45,48}

Vanderbilt University conducted a study (Doubleblind, randomized, placebo, controlled) in 240 volunteers to find a relation between green tea and blood cholesterol. 240 volunteers were adults and among them 120 volunteers took 375 mg of GT extract in the form of capsule (test group), while the remaining took placebo (placebo group), for a period of 12 weeks. A significant reduction in LDL cholesterol and total cholesterol (16.4\% & 11.3\%) found in test group than that of placebo group. Ingestion of 690 mg catechins for 12 weeks, reduces body fat and prevents obesity and other life style related diseases.\textsuperscript{45,49}

A Japanese study reported the use of green tea in depression. They conducted a test in 1,058 elder Japanese people having age of 70 years. Peoples taking green tea 4 cups per day have relatively very less depressive symptoms than that of people took 1 cup per day.\textsuperscript{45,50}
Sixty volunteers with High Grade Prostate Intraepithelial Neoplasia (HG-PIN), were treated with either 600 mg of green tea (test group) or placebo (placebo group). Test was conducted for a period of 1 year. Among the test group only one tumor was diagnosed, where as in placebo group 9 tumors were recognized. The study concludes a powerful point that green tea catechins are very safe and very effective for treating premalignant lesions before development of prostate cancer. Further green tea catechins also reduces urinary tract symptoms.\textsuperscript{51}

A Pilot Study of Chemo-prevention of Green Tea in Women with Ductal Carcinoma in Situ (DCIS) is one of the clinical ongoing projects in United States. It is an interventional, non-randomized study with end point of safety/efficacy. This study is sponsoring and conducting by University of Chicago. These clinical trials bear the number- NCT 01060345. The purpose of this study is to find molecular signs (biomarkers) to better understand the role of green tea in treatment of cancer and inflammation in women with newly-diagnosed ductal carcinoma in situ (DCIS). This study was started in February 2010 and expected to end in February 2012.\textsuperscript{52}

The role of natural green tea extract against hepatitis B virus was studied by using HBV cell line Hep G2-N 10. The 171µg/ml concentrated green tea solution able to kill 50% of viral cells. However, green tea extract which is rich with EGCG was showed a very weaker action against same virus cells.\textsuperscript{53}
A study reported that EGCG very effectively penetrated into human lung cancer cell lines PC-9, in presence of EC. Further EC works synergistically with Sulindac (synthetic cancer preventive agent) against the same cell lines. Consumption of green tea is effective in cancer prevention before its onset and even for its treatment.\textsuperscript{54}

Reiko Ide et al. conducted nationwide large scale cohort study in Japan. They reported the relation among oral cancer and green tea consumption. Women and men volunteers who do not have a history of oral cancer were selected for the study. The 29,671 women and 20,550 men having age range of 40-79 years were participated in the study. This study concluded the reduced risk of oral cancer in women, on consumption of green tea.\textsuperscript{55}

A study reported the antidote property of green tea in organ phosphorus pesticide poison in the rat liver. Green tea favors the recovery and reverses the damage sustained by pesticide exposure.\textsuperscript{56}

A study evaluates the comparative chemo preventive efficacy of green tea polyphenols and black tea polyphenols (DMBA) induced hamster buccal pouch (HBP) carcinogenesis. The status of antioxidant enzymes, lipid peroxidation, carcinogen metabolizing enzymes were used as biomarkers.\textsuperscript{57}

All green tea catechins especially EGCG arrest the cell cycle or induces apoptosis by suppressing oncogenic signaling pathways. They find that, EGCG suppresses the p53 dependent pathway in A549 cells.\textsuperscript{58}
Susana Coimbra et al. prepared a flavonoid rich infusion of *Camellia sinensis* and evaluated its efficacy in development of oxidative stress in plasma and in erythrocytes. The 34 Portuguese subjects were selected for this study. This research concluded the positive results of green tea and it protects the individual against development of oxidative stress diseases.⁵⁹

Ethanol extract of green tea was tested against human renal cancer cells A-498 and 769-P. This is the first report showing that green tea is likely to be an effective anticancer agent for renal cell carcinoma.⁶⁰

Green tea and Black tea aqueous extract prevents UV induced tumor formation by blocking oxidative DNA damage in animals. Thus both teas inhibits photocarcinogenesis.⁶¹

Green tea shows synergistic effect and additive effect with Sulindac and Tamoxifen respectively. A study reports that EGCG with Sulindac inhibits intestinal tumors in multiple intestinal neoplasia mice. Green tea extract and Sulindac were equally potential in the inhibition of tumor progress in mice.⁶²
2.2 SELENIUM

In some cohort studies, decreased ovarian cancer risk was associated with increased serum selenium concentration. A strong inverse relationship was observed between serum selenium levels and post menopausal breast cancer/colorectal/ uterine cervix cancers.\textsuperscript{34}

Most of the countries like India, China, Italy, Europe and US conducted the use of selenium (selenite or selenate) in human clinical trials. Such a China study reported an inverse relation between selenium serum levels and cervical cancer. A lower mortality of people from stomach cancer was observed during the ingestion of selenium in combination with β-carotene and α-tocopherol.\textsuperscript{34}

A study was conducted on smokers in India. A cocktail of selenium, zinc, vitamins A, C, and E, clearly protects the individuals against the development of oral lesions due to the reverse smoking. Large bowel adenoma cancer was effectively inhibited by selenium in a clinical trials conducted in Italy.\textsuperscript{34}

Australian Prostate Cancer Prevention Trial Using Selenium (APPOSE) is a clinical trial conducted by Australian government at Australia. Australian male adults, who are at high risk of prostate cancer, were actively involved in the study. APPOSE was aimed at checking of hypothesis that “either daily dietary selenium supplement will reduce the prostate cancer or not?”.\textsuperscript{39}
Nutritional Prevention of Cancer (NCP) group was conducted 10 years clinical trials at Arizona University. This is a placebo controlled, double blind and randomized study conducted in the year of 1996. This study demonstrated that 200µg of selenium supplement, in the form of yeast reduces prostate cancer risk by 63%.\textsuperscript{40}

Greeder and Milner compared the effectiveness of inorganic forms of selenium i.e., sodium selenite, sodium selenate or selenium dioxide with its organic form i.e., selenomethionine. They fed the selenium in the above forms in identical doses to the animals as supplement. They reported that, selenium inorganic forms are 8.3 times more effective than organic form, in inhibition of DMBA induced mammary tumors. Some studies found that selenomethionine supplements had no effect on Azoxymethane induced colon tumors. In a study sodium selenate, selenomethionine, se-methyl selenocysteine, and selenized yeast supplements were administered nude mice with in equivalent doses and separately. One million PC-3 prostate cancer cells injected directly into their prostate gland. None of the organic selenium supplements, retarded the prostate cancer growth. Sodium selenite salt reduces 43% of primary live cancer. Study was conducted at china 1,09,624 individuals were participated in the trial.\textsuperscript{40}

Redman and colleagues performed a study of selenium on 3 cancer cell lines i.e., Breast, prostate, and melanoma. Studied the effect of selenium on three tumor cell lines (Breast, melanoma, and prostate
They concluded that selenomethionine inhibits growth in both normal and cancer cell line in dose dependent manner. However, normal cells are 1000 times less sensitive to selenium selenomethionine.\textsuperscript{41}

Menter and coworkers reported that sodium selenite, which is the selenium inorganic form, is a more potent than selenomethionine.\textsuperscript{41}

A large clinical trials, which is involved 431 cases and 2459 subjects was conducted in the Netherlands and reported an inverse relation between toenail selenium concentration verses bladder cancer risk.\textsuperscript{41}

SELENIB is a randomized clinical trial started in 2007 by UK. SELENIB was aimed to investigate the action of selenium on reoccurrence and progression of bladder cancer. Nearly 1200 patients with non muscle invasive bladder cancer individuals were participated in the study. They received 200µg selenium yeast, 154mg tocopherols or placebo for a period of 5 years using a 2 X 2 factorial design. The results are expected to be report by the year 2012.\textsuperscript{41}

Nutritional Prevention of Cancer (NPC) trial was fed either placebo or 200µg selenised yeast every day to 1312 participants for a mean period of 4.5 years (SD ± 2.8). The results found that no association between selenium and skin cancer. However, there is a significant decrease in cancer incidents and mortality of lung, colorectal and prostate cancers.\textsuperscript{41}
Larry Clark et al. conducted a clinical trial on 1,300 older people, in the university of Arizona. This trial aimed “How effectively selenium inhibits the cancer”? Test group was fed with 200µg of selenium daily for a period of 7 years and another group was fed with placebo. Occurrence of cancer was decreased in test group 42% and deaths were cut by 50%.

Larry Clark et al. has conducted the most very exciting human trials in the America to find a protective role of selenium yeast against prostate lung and colon cancers. The individuals were supplemented with 200µg of selenium per day for a period of 4-5 years. The results are very positive to selenium and this element was successfully reduces the incidences of all above cancers. This Clark’s trail outcome encouraged the initiation of various trails throughout the world including SELECT (US) and PRECISE (Europe).

SELECT is a prestigious 12 years clinical trial project, currently going on in United States. It is a population based; placebo controlled, double blinded and randomized clinical trial funded by NCI. It is in Phase III stage, involving 32,500 men. Purpose of this clinical trial is testing the effectiveness of combination of dietary selenium with tocopherol against the development of prostate cancer. This is an outstanding effort towards finding novel approaches for the management of prostate cancer. This project was started in the year 2001 and results are expecting in the year 2013.
2.3 HERBOMINERAL FORMULATIONS

Kulkarni R R et al. prepared a herbomineral formulation. This formulation is consisting of *Withania somnifera* (roots), *Boswellia serrata* (stem), *Curcuma longa* (rhizomes), and Zinc. This formulation was evaluated in a cross-over, placebo controlled, double-blind, randomized study in patients who are suffering with osteoarthritis. The 42 patients were randomly instructed to take either the herbomineral formulation or equivalent placebo regularly for 3 months. Severity of knee pains were significantly dropped in test group.65

Mitra S K et al. prepared a herbomineral formulation named as D-400. They tested the same against blood sugar in streptozotocin induced diabetic rats. Urea, nitrogen, creatinine and uric acid, triglycerides, HDL cholesterol levels in the serum were significantly reduced. Further hepatic glycogen level become close to normal in test group.66

Subash Babu P et al. had developed a herbomineral formulation named Hyponidd. It is composed of 10 ten medicinal plants extracts, (*Melia azadirachta, Momordica charantia, Tinospora cordifolia, Pterocarpus marsupium, Gymnema sylvestre, Curcuma longa, Emblica officinalis, Eugenia jambolana, Cassia auriculata and Enicostemma littorale*). They chose the diabetic rats for the study. A significant blood glucose reduction and increased hepatic glycogen and blood hemoglobin was observed after oral administration of above said formulation for a period of 45 days at the dose of 100mg per kg body weight. 200mg of this
formulation is more effective than 600 μg of Glibenclamide. Further the formulation shows antioxidant property additionally.67

Mitra S K et al. had developed and evaluated osteo care herbomineral formulation called OST-6. It is indicated for the treatment of bone loss progress. Ovariectomized rats were selected for this study. Rats were supplemented with this herbomineral formulation for 90 days at the oral dose of 250 and 500 mg/kg body weight. In the next day after the study, the test group rats showed positive results. Hence the formulation can be used in the management of osteoporosis in natural way.68

Maji D and Singh A K, were developed D-400, which is a herbomineral preparation and consists of Eugenia jambulana, Ficus glomerulata, Pterocarpus marsupium, Gymnema sylvestre, Ocimum sanctum, Momordica charantia, and Shilajeet. They studied the effect of D-400 on blood sugar level, serum cholesterol, triglycerides, LDL, HDL, blood urea, serum creatinine levels and the effect of long term diabetic complications. This D-400 is shown to have beneficial effects as regards the long-term complications; its efficacy needs to be further evaluated. D-400 can serve as an important adjuvant in the treatment of diabetes.69,70

Datta G K et al. have developed a herbo mineral preparation, named Satavari mandur, which containing Asparagus racemosus. The formulation is indicated to protect ulcers. The cold restraint stress induced gastric ulcer rats were fed with this herbomineral formulation,
in the dose range 125-500 mg/kg through oral route. The results concluded that the formulation is effective against acute gastric ulcers but ineffective against ethanol and aspirin induced ulcers.71-80.
2.4 CONCLUSIONS DRAWN FROM LITERATURE

The following conclusions were made from the literature collected.

2.4.1 Conclusions about Green Tea

- Green tea leaves possess chemopreventive activity due to the presence of antioxidant catechins.
- Comparatively Green tea contains high catechins, and thus possesses high chemopreventive activity than other tea varieties.
- The strong antioxidant potential and chemoprevention activity of green tea catechins, especially EGCG, are widely demonstrated with Cell line, In-vitro, and In-vivo animal and In-vivo human studies.
- Green tea shows a potential cancer preventive activity against various types of cancers – Lung, Skin, G.I.T (Stomach, Intestinal, Colon, Rectal), Breast, Ovarian, Prostate.
- Green tea also possesses antimutagenic, antibiotic, anti-inflammatory, antibacterial and antiviral properties.
- Recent human studies suggest that green tea may contribute to reduce the risk of cardiovascular disease, body weight. Presence of caffeine strengthens polyphenol effects.
- The National Cancer Institute (NCI) of United States has sponsored a series of human intervention trials with individual phytochemicals (includes Green tea).
- Green tea is very effective against intestinal cancer. Further, it is having equal potency as that of Sulindac.
> Green tea shows synergistic effect and additive effect with Sulindac and Tamoxifen respectively.

> Since the synthetic cancer preventive agents are associated with adverse effects, there is a possibility of nontoxic, combination cancer chemoprevention with green tea.

**2.4.2 Conclusions about Sodium Selenite**

> Selenium ingestion protect the humans against all cancers, it had particularly powerful impacts on Prostate, G.I.T (Gastro, Intestinal, Colon, and Rectal), Lung, Breast, Cervix, Ovarian cancers.

> Various developing countries are conducting clinical trials for selenium in humans.

> Selenium in its various forms might have the potential to act throughout all stages of the carcinogenic way.

> People and animals having less selenium in their blood are at a higher risk of acquiring cancer than those whose blood contains more of this element.

> An intake of 150-300 µg of selenium daily is considered to adequate to protect the human organism without exhibiting the toxic properties of element.

> The National Cancer Institute (NCI) of United States has sponsored a series of human intervention trials with individual minerals (includes Selenium).