

## THE FORMULATION, DEVELOPMENT, AND EVALUATION OF AN IMMUNITY BOOSTER AIMED AT TO BOOST IMMUNITY DURING CANCER THERAPY

<sup>1</sup>\*Kamlesh S. Pathak, <sup>2</sup>Dr. Santosh Jain and <sup>3</sup>D. M. Waghmode

<sup>1</sup>Student, <sup>2</sup>Principal, <sup>3</sup>Professor

Aditya Institute of Pharmaceutical Beed – 431122.

Dr. Babasaheb Amedkar Technological University Lonere, Maharashtra, India.

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\*Corresponding Author: Kamlesh S. Pathak

Student, Aditya Institute of Pharmaceutical Beed – 431122, Dr. Babasaheb Amedkar Technological University Lonere, Maharashtra, India.

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### ABSTRACT

In recent years, there has been a noticeable shift towards herbal formulations over synthetic ones. While there are numerous herbal immunity boosters available in the market, there is a lack of options specifically tailored for cancer patients. To address this issue and mitigate the side effects of cancer therapy, it is imperative to develop an immunity booster using a combination of various herbal ingredients. Such as Ashwagandha, Cinnamon, Ginger, Guduchi, Coffee. The combination of these herbal ingredients produce an effect to minimize the side effect of cancer therapy. Use as WBC enhancer, Antitumor, Antibacterial, Antiviral, Antifungal.

**KEYWORDS:** Ashwagandha, Immunity boosters, herbal ingredients.

### INTRODUCTION

Cancer is a comprehensive term that refers to the condition where cellular changes lead to the uncontrolled growth and division of cells. Some types of cancer exhibit rapid cell growth, while others have a slower rate of growth and division. Certain forms of cancer result in the development of visible growths known as tumors, while others, like leukemia, do not. In the body, most cells have specific functions and lifespans. Cell death, also known as apoptosis, is a natural and beneficial process where a cell receives instructions to die in order to be replaced by a newer and more functional cell. However, cancerous cells lack the necessary components to stop dividing and undergo cell death. As a consequence, these cancerous cells accumulate in the body, utilizing oxygen and nutrients that would typically nourish other cells. They can form tumors, compromise the immune system, and cause various disruptions that hinder the normal functioning of the body. Cancerous cells may initially appear in a specific area and then spread through the lymph nodes, which are clusters of immune cells located throughout the body.

### Risk Factor

Preventable risk factors for cancer include Trusted Source:

- Smoking
- Heavy alcohol consumption
- Excess body weight
- Physical inactivity
- Poor nutrition
- Human papillomavirus infection

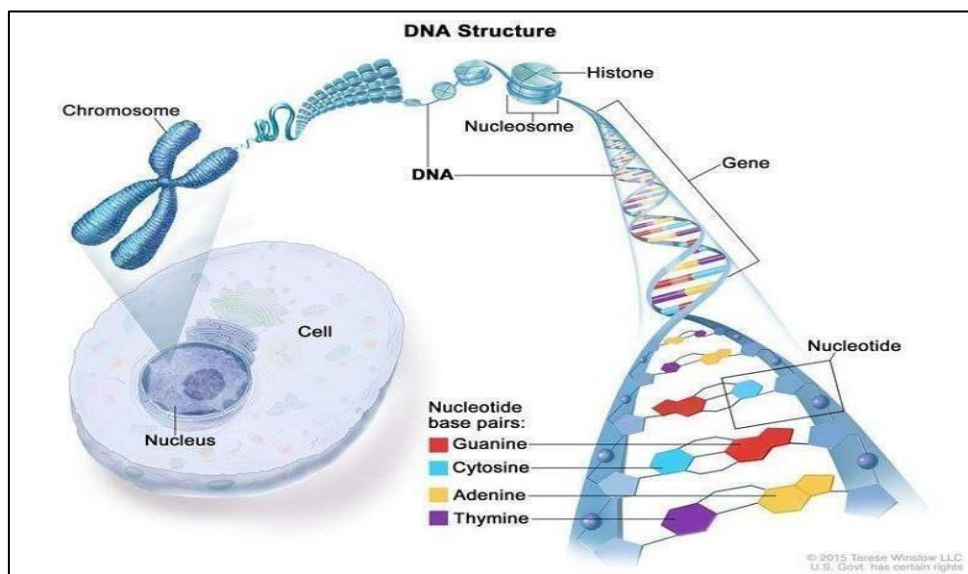
Other risk factors for cancer are not preventable. Currently, the most significant unpreventable risk factor is age. According to the American Cancer Society (ACS), doctors in the United States diagnose 88% Trusted Source of cancer cases in people ages 50 years or older.

### How Does Cancer Develop?

Cancer is a genetic disease that is, it is caused by changes to genes that control the way our cells function, especially how they grow and divide.

### Genetic changes that cause cancer can happen because

- Of errors that occur as cells divide
- Of damage to DNA caused by harmful substances in the environment, such as the chemicals in tobacco smoke and ultraviolet rays from the sun.
- They were inherited from our parents



The elimination of cells with damaged DNA by the body is typically a natural process that prevents them from becoming cancerous. However, this ability diminishes with age, leading to an increased risk of cancer later in life. Every individual's cancer is characterized by a distinct combination of genetic alterations. As the cancer progresses, further changes will occur. Even within a single tumor, various cells may exhibit different genetic modification.

### Cancer Treatments

Doctors typically prescribe treatments for cancer based on several factors, including the specific type of cancer, the stage at which it was diagnosed, and the overall health of the individual. There are various treatment options available for cancer, some of which include:

- **Chemotherapy:** This treatment involves the use of medications that target rapidly dividing cancer cells. While chemotherapy can help shrink tumors, it often comes with severe side effects.
- **Hormone therapy:** This approach involves taking medications that alter the functioning of certain hormones or interfere with the body's hormone production. It is commonly used for cancers like prostate and breast cancer, where hormones play a significant role.
- **Immunotherapy:** This treatment utilizes medications and other therapies to enhance the immune system's ability to fight cancer cells.
- **Radiation therapy:** High-dose radiation is used in this treatment to kill cancer cells. It may also be recommended to shrink tumors before surgery or alleviate tumor-related symptoms.
- **Stem cell transplant:** Particularly beneficial for blood-related cancers such as leukemia or lymphoma, this procedure involves removing damaged cells and strengthening them in a laboratory before reintroducing them into the body.
- **Surgery:** Often a crucial part of the treatment plan, surgery involves removing cancerous tumors. In some cases, lymph nodes may also be removed to prevent the spread of the disease.
- **Targeted therapies:** These treatments specifically target cancer cells to inhibit their growth and multiplication. They can also boost the immune system. Examples include small-molecule drugs and monoclonal antibodies.

### Side Effects of Cancer Treatment

- Neutropenia
- Lymphedema
- Hair Loss
- Nausea Vomiting
- Problem with thinking & remembering things

### Neutropenia (Low blood cell Count)

Neutropenia, a low count of neutrophils (a type of white blood cell), is a common side effect of cancer treatment, particularly chemotherapy. It increases the risk of infections. Patients might receive medications to stimulate white blood cell production or even adjust their treatment schedule to manage this. Regular monitoring and prompt treatment of infections are crucial. Neutropenia primarily increases the risk of bacterial infections, particularly those caused by common bacteria found in the environment, like Staphylococcus and Streptococcus. These infections can range from mild to severe and may affect various parts of the body, including the skin, respiratory tract, and bloodstream.

**Causes:** Bacterial Infection, Fungal Infection, Mouth Ulcer, Lack of energy.

### Role of Immunity Booster in Neutropenia

In neutropenia, where there's a low count of neutrophils (a type of white blood cell), immunity boosters can help support the body's defense mechanisms. These boosters typically include Ashwagandha roots, Ginger Rhizomes other

supplements that enhance the immune system's function, aiding in fighting infections and maintaining overall health. However, it's essential to consult with a healthcare professional before starting any immune-boosting regimen, especially in cases like neutropenia, as some supplements may interact with medications or exacerbate underlying conditions.

### Benefits of Immunity Booster

Immunity boosters can play a supportive role in cancer management by strengthening the body's natural defense mechanisms. They may help reduce the risk of infections during cancer treatment, enhance overall well-being, and potentially improve treatment outcomes. However, it's essential to consult with healthcare professionals before incorporating any supplements or immunity boosters into a cancer treatment plan, as they can interact with medications or treatments. In neutropenia, where there's a low count of neutrophils (a type of white blood cell), immunity boosters can be particularly beneficial. They help bolster the immune system, reducing the risk of infections which can be more severe in individuals with neutropenia due to their weakened immune response. This added protection can be crucial during cancer treatment when the immune system is often compromised. Nonetheless, medical guidance is essential to ensure any interventions are safe and appropriate for the individual's specific condition.

### Plant Profile

#### 1) Ashwagandha

Drug consists of dried roots of *Withania somnifera* (Linn.) Dunal (Syn. *Physalis Somnifera* Linn., *P. Flexuosa* Linn., *P. Arborescence* DC.); Fam. Solanaceae. The Plant is widely distributed in North-Western India, Bombay, Gujrat, Rajasthan, Madhya Pradesh, Uttar Pradesh, Punjab plains and extends to the mountain regions of Himachal Pradesh and Jammu.

### Chemical constituents

The majority of the constituents are withanolides (steroidal lactones with ergostane Skeleton) and alkaloids. These include Withanone, Withaferin Withanolides I, II, III, A, D, E, F, G, H, I, J, K, L, M, WS-I, P and S, withasomidienone, withanolide C", and alkaloids" viz., cuscohygrine, anhydride, tropine, pseudotropine, anaferine, Isopellatierine, 3-tropylogloate. Total alkaloids about 0.2%



### Uses

- Roots of the plant show antitumor and radio sensitizing effects in animal models
- Total alkaloidal fraction of the root extract exhibits hypotensive, bradycardic, and Respiratory stimulant activities in dogs.
- It shows relaxant and antispasmodic effects against several plasmalogenes on intestinal, uterine, bronchial, tracheal, and Blood vascular muscles.

## 2) Ginger

### Chemical Constituents

Oleoresin (-5.3 -8.6%) comprising of nonvolatile pungent principles (gingerols mainly [6]- gingerol), non-pungent substances (fats and waxes), and Volatile oil (-1.5 – 2.2%) containing sesquiterpene hydrocarbons viz..azingiberene, B-sesquiphellandrene and ar-curcumin as major constituents (The composition of volatile oil varies according to origin” 10- and changes upon storage”). Lipids (-6-8%) Proteins (-10%) Starch (~ 40-60%).



## 3) Cinnamon Bark

Kalmi- Dalchini, Ceylon Cinnamon Cinnamon consists of the dried inner bark of the shoots of coppiced trees of *Cinnamomum Zeylanicum* Nees belonging to the family Lauraceae. It should not contain less than 1.0% of volatile oil.

Cinnamon bark contains about 0.5 to 1% of volatile oil, 1.2% of tannins, mucilage, calcium oxalate, starch, and a sweet substance known as mannitol. The volatile oil is the active constituent of the drugs. It is light yellow in color and changes to red on storage. Bark yields 14 to 16 % of 90% alcohol-soluble extractive.



Cinnamon oil contains 60 to 70% of cinnamaldehyde, 5 to 10% eugenol, benzaldehyde, cumin aldehyde, and other terpenes like phellandrene, Pinene, cymene, caryophyllene, etc. Cinnamon oil is yellow to red.

**Uses**

- The bark is used as a carminative
- Stomachic, and mildly astringent.
- It is also used as a flavoring agent, stimulant, and aromatic and antiseptic
- Commercially, it is used as a spice and 29 condiments, and also in the preparation of candy, denitrifies, and perfume

**4) Guduchi**

Guduchi which goes by the scientific name *Tinospora cordifolia* is an extremely essential immunomodulator herb and a base ingredient of numerous Ayurvedic formulations. Deemed as 'Queen Of Herbs', Guduchi plays a significant role in the promotion and restoration of health and curing several diseases and infections.

In Sanskrit, Guduchi means "a herb that protects the body from diseases" and points to a Hindu myth that praises Guduchi for offering the gift of life and eternal youth to celestial beings. It is mentioned in several ancient scriptures about being extensively used for the treatment and management of numerous health aberrations like fever, chronic fever, infections, low immunity.

**Chemical constituents**

The therapeutic properties of Guduchi to treat a host of diseased conditions show that the herb is replete with essential nutrients. The abundance of alkaloids, flavonoids, carbohydrates, steroids, lignans, and potent active constituents like tinosporin, ethanol, isocolumbin, tembetarine, palmetin, choline, berberine, mangoflorine, aporphine increases the curative efficacy of the herb and truly makes it a class apart. Owing to its high nutritional content, Guduchi is illustrated in several ayurvedic scripts as one of the most used ayurvedic herbs in formulating different types of ayurvedic, herbal and modern-day medications.

**Uses**

Immunomodulator, Anti-inflammatory, Mild Analgesic, Antioxidant, Anticancer, Anti-stress, Carminative, Digest.

**5) Coffee**

Coffee bean, coffee seed, Arabica coffee, Arabian coffee, Abyssinian coffee, Brazilian coffee.

It is the dried ripe seeds of *Coffea arabica* Linn, belonging to family Rubiaceae.

**Chemical Constituents**

The main constituents of coffee are caffeine, tannin, fixed oil and proteins. It contains 2–3% caffeine, 3–5% tannins, 13% proteins, 10–15% fixed oils. In the seeds, caffeine is present as a salt of chlorogenic acid. Also it contains oil and wax.



### Honey

**Synonym-** Shahad

### Biological source

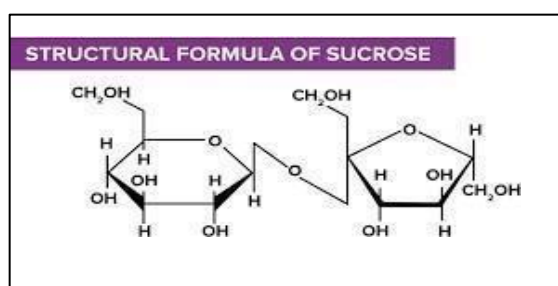
It consists of saccharine liquid prepared from the nectar of the flowers by the Honey-bee *Apis mellifica* belonging to family Apadae.

### Chief chemical constituents

Dextrose and laevulose (70-80%) Dextrin proteins

### Uses

Honey possesses natural antibacterial and antiviral properties, which makes it an excellent candidate for improving your immune system and Antioxidant content, which fights free radicals.



### Sucrose

The word sucrose was coined in 1857, by the English chemist William Miller from the French sucre ("sugar") and the generic chemical suffix for sugars -ose. The abbreviated term Suc is often used for sucrose in scientific literature. The name saccharose was coined in 1860 by the French chemist Marcellin Berthelot. Saccharose is an obsolete name for sugars in general, especially sucrose.

**MATERIAL AND METHODOLOGY****1) For powder dosage form**

Ingredients	Role	F1	F2	F3
Ashwagandha	Antitumor Antibacterial	10gm	16gm	16gm
Cinnamon	Stimulating agent Flavoring agent	10gm	9gm	16gm
Ginger	Antiulcer Digestive aid	10gm	16gm	9gm
Coffee	CNS stimulant Immunity Booster	10gm	9gm	9gm

**2) For liqued (syrup) dosage form**

Ingredients	Role	F1 (EXTRACT)	F2 (EXTRACT)
Ashwagandha	Antitumor Antibacterial	14ml	5.5ml
Cinnamon	Stimulating agent Flavoring agent	14ml	5.5ml
Ginger	Antiulcer Digestive aid	14ml	5.5ml
Coffee	CNS stimulant Immunity Booster	14ml	5.5ml
Guduchi	Anti inflammatory Antibacterial	14ml	--
Honey	Adhesive agent Antibacterial	14ml	11ml
Sucrose	-	166.75ml	33.35ml

**Method**

The Multi Herbal Immunity Booster was made according to the formula present below:

**Power Formulation****Step 1: Selection of Herbs**

Select herbs according to their therapeutic properties and the benefits they provide in order to boost the immune system of individuals with cancer.

**Step 2: Prepare Herb (POWDWR)**

Choose herbs, grind them into a fine powder using a mortar and pestle, and then sift through a sieve number 44.

**Step 3: Mixing Herbs**

The blending of powders with a spatula on a tile or paper sheet used sometimes for small quantities and with the help of mortar and pestle technique.

**Step 4: Evaluation Parameter**

- Colour
- Odour
- Taste
- Tap Density
- Bulk Density
- Angle of Repose
- Water-Soluble extractive Value

**Step 5: Labeling**

- Brand Name
- Active Ingredients
- Dosage
- Warnings



- Storage
- Expiry Date

**Images of Formulation and Evaluation**



**Liquid Dosage Formulation (Syrup)**

**Step 1: Selection of Herbs**

Select herbs according to their therapeutic properties and the benefits they provide in order to boost the immune system of individuals with cancer.



**Step 2: Prepare Herb (PODWR)**

Choose herbs, grind them into a fine powder using a mortar and pestle, and then sift through a sieve number 44.



**Sieve**



**Mortal Pestel**

**Step 3: Extraction****Prepare extract using maceration and Soxhlet method**

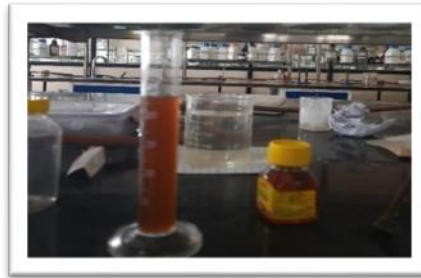
Take a beaker neat and clean and add all powder in required quantity. Add required quantity of water in powder. Boil the mixture for 3 to 4hrs. Filter the solution using Filter paper and muslin cloth then collect liquid extract and store in air tight container.

**Soxhlet Extraction****Maceration****Extract****Step 3: Preparation of Simple Syrup**

To prepare simple syrup take 100ml water and add 66.7gm sucrose and heat in water bath for 30 min and stir until sucrose dissolves completely.

**Step 4: Final Formulation**

Add the extract to the simple syrup following the standard formula, then proceed to create the final formulation and carry out an evaluation study of the product.

**Final Syrup Formulation****Step 5: Packaging**

Store herbal powder in airtight containers to protect from moisture.

**RESULT**

The Immunity Boosters come in both powder and liquid forms, making them easy to administer orally. The formulated Immunity Boosters are assessed based on various physical properties.

**Powder Formulation****Organoleptic Properties**

- a) Colour - Light Brown
- b) Odour - Characteristic
- c) Taste - Bitter

**Tap Density**

The measurement of Tap Density of the formulation were done and it was observed that the tap density of formulation F1 to F3 was found to be range 0.60gm/ml to 0.64gm/ml.

**Bulk Density**

The measurement of Bulk Density of the formulation were done and it was observed that the tap density of formulation F1 to F3 was found to be range 0.457gm/ml to 0.499gm/ml.

**Angle of Repose**

Under the static balance, the Angle between the slope of a powder pile and the horizontal plane was observed. Angle of repose of Formulation F1 to F3 was found to be range 20 degree to 25 degree.

**Water Soluble extractive Value**

Took 5 gm of the powder sample of the herbal drug in a conical flask and 90ml of water and added 10ml of chloroform and kept it for magnetic stirring for 6 hours then placed it for 18 hours. Filtered it and took 25 ml of filtrate from that evaporated it.

Observation: 4.8%

**Alcohol soluble extractive value**

Took 5gm of the powder sample of herbal drug mixture in a conical flask added 100ml of alcohol into it kept it for magnetic stirring for 6 hours then placed it for 18 hours filtered and took 25 ml of filtrate from that evaporated it.

Observation: 5.2%

**Syrup Formulation****Organoleptic Properties**

- a) Colour - Light Brown
- b) Odour - Characteristic odour
- c) Taste - Bitter

**pH Determination**

Placed an accurately measured amount 10 ml of the final syrup in a 100 ml volumetric flask and made up the volume up to 100 ml with distilled water. The solution was sonicated for about 10 minutes. pH was measured with the help of digital pH meter. Observation: 5.2 to 6.5

**Consistency**

Clear solution No solid particles found

**Specific Gravity**

Weight of empty density bottle (A)= 17.70 gm

Weight of density bottle with Syrup (B) - 29.58 gm

Weight of Syrup B-A

= 29.58-17.70

= 11.88 gm

Therefore, weight of 10 of Syrup = 11.88 Therefore, Density of Syrup - Mass/ Volume

= 11.88 / 10 = 1.18 gm/ml

**CONCLUSION**

In recent years, there has been a noticeable shift towards herbal formulations over synthetic ones. While there are numerous herbal immunity boosters available in the market, there is a lack of options specifically tailored for cancer patients. To address this issue and mitigate the side effects of cancer therapy, it is imperative to develop an immunity booster using a combination of various herbal ingredients. Such as Ashwagandha, Cinnamon, Ginger, Guduchi, Coffee. The combination of these herbal ingredients produce an effect to minimize the side effect of cancer therapy. Use as WBC enhancer, Antitumor, Antibacterial, Antiviral, Antifungal

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