DEVELOPMENT OF HERBAL FORMULATIONS USING NATURAL BLOOD PURIFIER FOR THE TREATMENT OF CHRONIC SKIN DISEASES

Submitted to



Submitted by

SCHOOL OF PHARMACEUTICAL SCIENCES FACULTY OF HEALTH SCIENCES ATMIYA UNIVERSITY, RAJKOT

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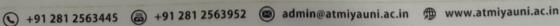
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DECLARATION

We, all hereby declare the Work is presented in the project report entitled Development of herbal formulations using natural blood purifier for the treatment of chronic skin diseases.

It is an authentic record of work carried out by us during the studying period of semester 8 at and under the guidance of Atmiya University, Rajkot, and is being submitted for partial fulfillment of the requirement for the award of a bachelor's degree in B.pharm. This is not submitted anywhere else for the award of any other degree/diploma.

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I'd like to thank The ATMIYA UNIVERSITY for providing us with the opportunity to work on the project (Development of Herbal formulations using natural blood purifier for the treatment of chronic skin diseases). Last but not least, I would like to express my gratitude to our other faculty members, family, siblings, and friends for their invaluable assistance, and I am deeply grateful to everyone who has contributed to the successful completion of this project.

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ABSTRACT

The skin diseases are prevalent. The root cause of many skin diseases is the presence of toxins and impurities. Impure blood is not only responsible for skin diseases but it poses many other health issues. The present work is intended to prepare an herbal formulation to purify the blood. Medicinal plants have curative properties due to the presence of various complex chemical substance of different composition, which are found in one or more parts of these plants Amla (Emblica officinalis) and Beetroot (Beta vulgaris) used as blood purifier for the treatment of chronic skin diseases. The present work deals with formulation and evaluation of blood purification activity of tablets prepared from extract of the selected plant. A solid pharmaceutical dosage formulation using a plant extract using excipients viz., honey by direct compression was reported blood purification activity. The present work also deals with the evaluation of formulated tablets (weight variation, friability, hardness and disintegration time).

INTRODUCTION

From ancient times, people have utilized herbal or plant-based treatments to prevent and treat illnesses. Many of the components of these natural sources are still unknown today. This has encouraged scientists to find new chemicals in herbal sources to treat various viral illnesses. Most medicinal plants include antibacterial, antioxidant, and anti-inflammatory properties, according to research. These abilities may also have significant societal benefits in addition to opening the door for the avoidance of many infectious diseases. The incidence of newly developing and reemerging infectious diseases has dramatically grown, according to the current condition of infectious illnesses. The development of antibiotic resistance in medical environments is a serious concern. Thus, there is a pressing need for a natural solution that can fight the skin ailments.

Blood is a fluid form of connective tissue and consist of cells. The cells are present in the blood are-Red blood cells, White blood cells and blood platelets thrombocytes. Plasma consists of some proteins known as plasma proteins such as albumins, globulins and blood clotting proteins. It transports carbon dioxide from every part of the body to the lungs and oxygen from the lungs to every part of the body, it is referred to as the "fluid of life." The reason it is called "fluid of growth" is that it transports hormones from endocrine glands and nutrients from the digestive system to every tissue in the body. Because it shields the body from illness and removes waste and undesirable chemicals by moving them to the kidney or other excretory organ, blood is known as the "fluid of health."

Herbal medicine is the oldest known medical practice in human history. Every society throughout history has made use of herbs. It was essential to the development of modern civilization. The production of blood becomes impaired and digestion is made more difficult when the liver stops functioning. There are toxins in our food, air, and daily lives on a regular basis. Apart from herbs that are used as blood purifiers and substitutes food additives, water pollution, and inadequate nourishment are other reasons that cause the liver to become overworked. Herbs aid in blood purification by break down the internal toxins. Herbs assist in purifying the blood by dissolving internal pollutants. Herbs have been utilized for many disorders since ancient times, such as blood purification and the removal of toxins from the kidney, liver, and lymphatic system.(Chandira & Jayakar, n.d.)

SKIN

Anatomy of skin

Human skin comprises of three but mutually dependent tissues:

The stratified, vascular, cellular called as "epidermis".

Underlying dermis of connective tissues.

Epidermis

The epidermis of the skin is formed by stratified epithelium, which is made up of 1 layers:

- 1. Stratum corneum.
- 2. Stratum lucidum
- 3. Stratum granulosum
- 4. Stratum spinosum and
- 5. Stratum germinativum

The absence of blood vessels in the epidermis is its most significant characteristic. The dermis's capillaries supply the nutrients. The top layer of skin, called the epidermis, is a stratified, squamous, keratinizing epithelium. Keratinocytes, which are responsible for the skin's barrier properties, make up more than 90% of the cell population.

Dermis

The next layer of skin, the dermis, is made up primarily of collagen, elastin, and fibrillin, which give it its strength and flexibility. The dermis is made up of blood vessels, nerve endings, sweat glands, oil glands, and hair follicles. The dermis is a vascularized, collagenrich connective tissue that also contains the ground substance, a group of mucopolysaccharides.

Hypodermis

The hypodermis is the skin's innermost layer. It is the layer of skin that comes into contact with the body's deeper tissues, like muscles and bone. Sebaceous glands, sweat glands, and hair follicles all originate in the dermis but are enclosed in the epidermis. A thin salt solution is injected into the skin's surface by sweat glands. In order to regulate body and skin temperatures, the evaporation of this diluted salt solution cools the skin. The body contains sweat glands all around. The amount of dilutions (sweat) created is influenced by the temperature of the environment, the level of heat-producing skeletal muscle activity, and a variety of emotional aspects. Sebum is an oily substance that enters hair follicles before leaving them and reaching the skin's surface. Sebum defends both hair types.(Havlickova et al., n.d.)

Function of skin:

Skin plays a significant part in defending (the body) against infections and excessive water loss since it interacts with the environment. Other roles include water resistance, temperature regulation, feeling, storage, protection of vitamin B folates, absorption of oxygen and medications, and production of vitamin D by the action of ultraviolet (UV) light. Skin that is severely damaged will attempt to recover by producing scar tissue. This is frequently depigmented and discoloured.

Skin infection:

Skin invasion by pathogenic germs or normal skin flora is prevented by an unbroken stratum corneum. Skin ailments that are frequently worse by secondary bacterial invasion can be generally divided into those that cause itching and that can be spread by scratching, like scabies and pediculosis, and those that lack a skin barrier, such eczema, pemphigus, and ulcers. It is crucial to identify secondary infections to skin lesions as soon as possible and to properly treat them medically and surgically because they can be potentially fatal and spread quickly

Chronic skin diseases:

Skin conditions are a prevalent ailment that can injure a person in various ways and affect people of all ages, from newborns to the elderly. Although there are more than a thousand illnesses that can damage the skin.

Eczema:

Eczema is a common, chronic, non-infectious skin condition. The main symptom of this inflammatory disease is a very itchy rash. It often affects children. In many cases eczema gets better as the years go by, and it may go away for a while or disappear altogether. Acute flare-ups can really affect quality of life. The itching can be especially bad, making it difficult to concentrate and sleep well. Some people are embarrassed if their rash is visible to others. By taking good care of your skin, using medication and avoiding irritants and other things that can trigger the eczema, it is usually possible to relieve the symptoms at least enough to live a fairly normal life. Eczema is sometimes also called "atopic eczema" or "atopic dermatitis."

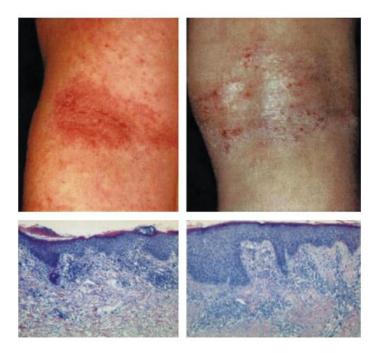


Figure 1: Clinical (upper) and histological (lower) findings in acute and chronic atopic dermatitis

Symptoms:

Symptoms of acute eczema include red and itchy skin, sometimes with blisters that easily break and then weep (leak liquid). Over time the skin may become dry and cracked, and also thicken. Its structure may also change, making it rougher. The main symptom is itching, which can often become unbearable.

The typical affected areas of skin, as well as the intensity of symptoms, differ from person to person and are also dependent on age. Eczema primarily affects the cheeks, the outside parts of the arms and legs, and, less frequently, the back, stomach, and chest. The backs of knees, inside elbows, and backs of necks are the most frequently afflicted areas for

children, teens, and adults with eczema. Additionally, the soles of their feet and the palms of their hands may get the itchy rash. Faces are rarely affected.

Pathogenesis:

The clinical term eczema and the pathologic term dermatitis are synonyms. Both speak of an inflammatory reaction to different substances operating on the skin from the inside or outside of the body, such as medications and chemicals, as well as hypersensitivity to different antigens. Consequently, a variety of clinical forms are documented, including drug-induced dermatitis, photo-eczematous dermatitis, atopic dermatitis, contact dermatitis, and primary irritant dermatitis. This category also includes a large number of idiopathic forms of skin diseases, including neurodermatitis (lichen simplex chronica), exfoliative dermatitis (erythroderma), seborrheic dermatitis, and pompholyx. Clinical symptoms of these disorders typically include scaling, oozing, erythema with oedema, and itching. However, irrespective of the clinical type of dermatitis, the histopathologic picture is similar. Histologically, dermatitis reaction may be acute, subacute or chronic.

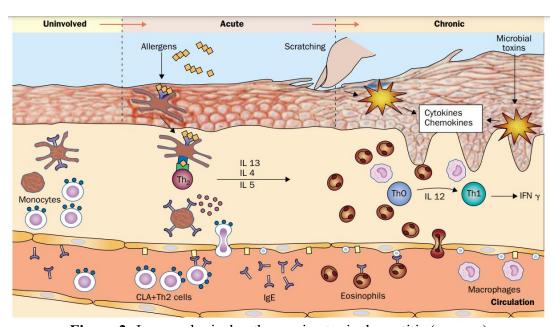


Figure 2: Immunological pathways in atopic dermatitis (eczema)

- Acute dermatitis is characterized by considerable spongiosis (intercellular oedema) that may lead to formation of intraepidermal vesicles or bullae. Acute inflammatory cells penetrate the vesicles, bullae, and oedematous epidermis. The upper dermis shows congested blood vessels and mononuclear inflammatory cell infiltrate, especially around the small blood vessels.
- After acute dermatitis, subacute dermatitis may occur. Vesicles and spongiosis have smaller than in cases of acute dermatitis. The horny layer of the epidermis exhibits different degrees of parakeratosis and moderate acanthosis, along with the production of surface crusts that include fibrin, bacteria, and degenerated leucocytes. Perivascular

mononuclear infiltration is present in the dermis. Nummular dermatitis is a classic example of subacute dermatitis.

The symptoms of chronic dermatitis include hyperkeratosis, parakeratosis, and acanthosis, along with enlarged cutaneous papillae and rete ridge elongation. There may be a small spongiosis present, but there are no vesicles. Perivascular chronic inflammatory infiltration and fibrosis are visible in the upper dermis. Lichen simplex chronic is the most characteristic example of chronic dermatitis. (Havlickova et al., n.d.)

Ringworm:

Ringworm is a common infection of the skin and nails that is caused by fungus. The infection is called "ringworm" because it can cause an itchy, red, circular rash. Ringworm is also called "tinea" or "dermatophytosis." The different types of ringworm are usually named for the location of the infection on the body.

Areas of the body that can be affected by ringworm include:

- o Feet (tinea pedis, commonly called "athlete's foot")
- o Groin, inner thighs, or buttocks (tinea cruris, commonly called "jock itch")
- Scalp (tinea capitis)
- o Beard (tinea barbae)
- o Hands (tinea manuum)
- o Toenails or fingernails (tinea unguium, also called "onychomycosis")
- Other parts of the body such as arms or legs (tinea corporis)

Approximately 40 different species of fungi can cause ringworm; the scientific names for the types of fungi that cause ringworm are Trichophyton, Microsporum, and Epidermophyton.'

Symptoms:

Symptoms vary depending on where the infection occurs. With a skin infection, you may experience the following:

- Itchiness
- Itchy or scaly patches that are red, brown, or Gray, or raised areas of skin called plaques
- A round, flat patch of itchy skin
- Patches that develop blisters or pustules
- Patches that resemble a ring with deeper colour on the outside
- Patches with edges that are defined and raised
- Overlapping rings
- Hair loss

Rationale Behind the Study:

The modern lifestyle has had a significant impact on our daily routine and has resulted in drastic changes to our eating habits and way of life. However, the increasing levels of environmental pollution have had a profound impact on us both internally and externally. There are toxins in our food, air and daily lives on regular basis. They reduce or impaired function of liver and kidney, which leads to impure blood. It also causes chronic skin diseases.

Furthermore, blood purifiers have been touted as effective against cancer, allergies, body odour, and toxin buildup. It is said that blood purifiers help the body rid itself of toxins by either supplying nutrients to enhance blood function or stimulating the liver, kidney, or lymphatic system through neutralization in the blood. Our blood is already highly purified by the liver and kidneys through the removal and breakdown of waste. So, the greatest course of action for naturally cleansing the blood would be to figure out how to support the optimal functioning of these vital organs.

Since ancient times, people have used herbs for a variety of ailments, including as purifying the blood and eliminating toxins from the kidney, liver, and lymphatic system. It encourages the kidney's and liver's inactive functions to become more active and healthier. Our skin becomes healthier as our system becomes purer. We employ curcumin as a powerful medication in our investigation. It's a fantastic blood purifier. Its antioxidant qualities shield the body from free radicals and cancer. Additionally, because of its anti-inflammatory qualities, it lessens inflammation and the buildup of excess toxins in blood vessels. We also utilize powdered amla, which has potent antioxidant properties and helps with digestive disorders. It serves as a hepatoprotective as well.

We use beet root powder because it provides nitrates, which dilate blood vessels. It also has hepatoprotective effects. They don't hurt the body because they are natural blood purifiers. It eradicates the illness from its underlying cause, reducing the likelihood of recurrence. Therefore, an attempt has been made in the current study to create a herbal formulation for the treatment of chronic skin illnesses utilizing a mixture of these three natural blood purifiers. (Phytomedicine, n.d.)

OBJECTIVES:

- To identify herbs for blood, purify.
- To identify of part of selected herbs.
- To prepare dosage form containing blood purifier.
- To evaluate of dosage form.
- (Objective of the current study is to prepare blood purifier vati and tablet for the purpose of treatment of chronic skin disease.)
- (Primary objective of blood purifier is to remove toxic material & chemical from blood and purify the blood.)

MATERIALS AND METHODS

Material we generally considered to use in our formulation as following (Tadeg et al., 2005) (van Vuuren & Frank, 2020):

Table: 01 Herbs and their uses	
HERBS USE OF HERBS	
Amla powder	Antioxidant,
Beet root powder	Anticancer, Antihyperlipidemic, Vasodilator
Sariva	Anti-inflammatory, Antioxidant, Free radical
	scavenging
Manjistha	Antibacterial, Anti- inflammatory, Stimulate blood
	circulation.

Chopchini	Blood cleanser, Immune modulator, Antimutagenic,
	Detoxifier.
Harida	Antioxidant, Anti- inflammatory
Neem	Anticeptic, Antibacterial, Anti- inflammatory
Ginger	Antioxidant, Antimicrobial, Antidiabetic,
	Cardiovascular protection.
Mulethi	Anti- inflammatory, Antimicrobial.
Mundi	Immunomodulatory, Anti- inflammatory,
	Hepatoprotective

Through these all are beneficial herbs we use as following herbs in our herbal formulation:

Plant material:

1. Emblica officinalis:



Figure: 03 Amla powder

Emblica officinalis (Amalika) is most widely and important plant in Indian traditional system, family of Euphorbiaceae and also known as Phyllanthus emblica and Indian gooseberry. It increases immunity against disease, beneficial role in digestive disease like cancer, diabetes, liver treatment, ulcer, anemia, eye disease and skin diseases.(Gantait et al., 2021)

Chemical composition:

- It contains 20 times more vitamin c compares to orange juice.
- It contains calcium, phosphorous, riboflavin, iron, carotene, thiamin, besides vitamin c.
- Stronger Antioxidant properties to its small molecular weight tannoid complexes. (Bhagat, n.d.)

Benefits of amla:

- Antiaging
- Heart burn
- Liver protection
- Immune health
- Antimutagenic

- Antineoplastic
- Anti-diabetes
- Antidepressant

Nutrition value in 100mg:

- Energy 58 kilo calories
- Fiber (3.4%)
- Proteins (0.5%)
- Fat (0.1%)
- Carbohydrates (13.7gm)
- Calcium (50%)
- Iron (1.2gm)
- Carotene (9 microgram)
- Thiamine (0.03mg)
- Riboflavin (0.01mg)
- Nicene (0.2mg)
- Vitamin (600mg) (Bhat Scholar et al., 2019)

2. BETA VULGARIS:



Figure: 04 Beetroot powder

BETA VULGARIS (Beet) belong to Ambaranthaceae family. According to scientific study on beet the consumption of this plant is direct reduce the risk of obesity, diabetes mellitus, cardiovascular disease. Also used in cancer treatment. Ingestion of beet root is natural source of nitrate, increases the availability of nitric oxide. Beet root is one of the reaches source of folate. It contains vitamin a, b, b1, b2, b6, c. It also good source of calcium, magnesium, copper, phosphorous, sodium, iron. Beet root have long been use of medicinal purpose. Use in primary disorder of liver as they help to stimulate the liver detoxification process. Plant pigment that gives beet root its rich purple crimson color is betacyanin. (Chen et al., 2021) (Mudgal et al., 2022)

Chemical constituent:

Nitrate

Development of Herbal formulations using natural blood purifier for the treatment of chronic skin diseases

- Phenolics
- Ascorbic acid
- Carotenoids
- Betalains (butacaines, betaxanthins, betanin iso betanin)
- Flavonoids
- Phenolic acids
- Phenolic amides

Health benefits:

- Lower blood pressure and increase blood flow
- Antitumor activity
- Hepatoprotective
- Antihyperglycemic
- Improve brain function
- Anti-inflammatory activity
- Antimicrobial activity (Baião et al., 2020)

Composition percentage:

Constituent	Percentage
Phosphorous	40mg
Calcium	16mg
Magnesium	23mg
Iron	0.80mg
Zinc	0.35mg
Vitamin c	4.9mg
Vitamin b2	0.04mg
Vitamin b6	0.067mg
Folacin	109mg
Niacin	0.334mg

CURCUMIN:



Figure: 05 Curcumin powder extract

CURCUMIN (Curcuma longa or turmeric) rhizome and other Curcuma spp. Curcuma longa's traditional uses have been attributed to its antioxidant, anti-inflammatory, antimutagenic, antibacterial, and anticancer properties. Curcumin also known as diferuloylmethane, is the main naturally occurring polyphenol that is being used as a medicinal plant in Asian countries to treat a wide range of illnesses.

The solubility of curcumin can be observed in both extremely acidic and alkali solutions. The bright orange-yellow crystalline material is utilized as a food coloring agent. It's a keto-enol tautomeric compound with strong metal ion chelating properties. Whereas the enol form is important in alkalis solutions, the keto form is more prevalent in acidic or neutral solutions. Different activities of curcumin have been directly associated with its keto or enol forms. (Vollono et al., 2019)

Research conducted over the past fifty years has shown that the main active ingredient in Curcuma longa is curcumin, which may help prevent diabetes, allergies, arthritis, Alzheimer's disease, and other chronic illnesses. Beyond curcumin, Curcuma longa also contains additional chemicals that belong to the category of molecules known as curcuminoids. Their names are dimethoxy curcumin and bis-dimethoxy curcumin. The group of compounds known as curcuminoids, of which curcumin makes up 77% of the total weight, makes up about 5% of Curcuma longa. Based on their structures, some studies have hypothesized that the methoxy groups on the phenyl rings of curcumin are crucial to its health benefits. Moreover, it has been documented that several curcuminoids function together, such as This review's objective is to increase our comprehension of curcumin's effects on health and to elucidate the different methods in which it functions to treat different ailments. (Vaughn et al., 2016)

Chemical structure:

Beneficial role:

Decrease the outcome of increased cell proliferation and curcumin's effective free-radical scavenging. The addition of curcumin also increased collagen's thermostability. Curcumin also reverses oxidative damage to fibroblasts, skin cells, and keratinocytes. Curcumin shields keratinocytes from hydrogen peroxide's oxidative damage at a concentration of 10 g/ml. Early growth response-1 gene is a transcription factor that controls genes related to wound healing and the vasculature, among other pathological processes. It may have a role in the intricate chain of cellular and thrombogenic processes that lead to the formation of vascular occlusive lesions. Because curcumin inhibits the production of Egr-1 in fibroblasts and endothelial cells, it may be useful as a therapeutic agent, especially in preventing thrombogenic events linked to a number of

clinical disorders. The verbal and the application of topical curcumin to punch biopsy wounds accelerated their healing process. Treatment with curcumin led to enhanced collagen deposition, widespread neovascularization, increased migration of myofibroblasts, fibroblasts, and macrophages in the wound bed, and quicker epidermal re-epithelialization. This improved wound-healing activity is linked to curcumin's upregulation of TGF-1 expression. These investigations demonstrate the efficaciousness of curcumin as a medicinal agent to promote wound healing. (Krup et al., 2013)(Kumar & Kumar Sakhya, 2013)

Mechanism:

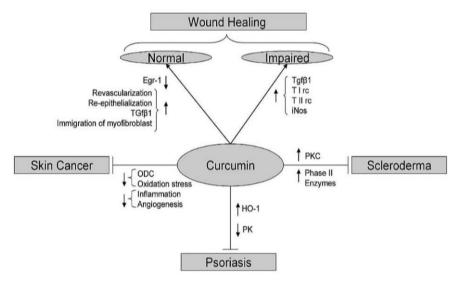


Figure: 06 Mechanism of curcumin in skin diseases

Metabolite Derivatives:

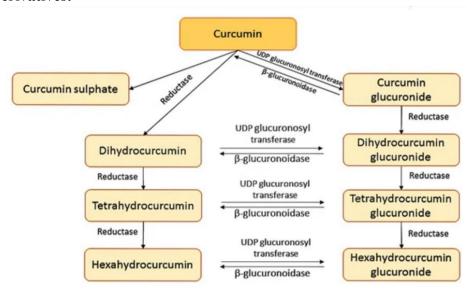


Figure: 07 Metabolite Derivatives of curcumin

HONEY:



Figure: 08 Honey

HONEY is by product of flower nature and the upper aero-digestive tract of the honey bee. Which is concentrated through dehydration process inside the bee hive. Honey is most appreciated and valued natural products, introduce to human kind since ancient times. Honey is not only as a nutritional product but also in health described in traditional medicine and as a alternative treatment and clinical condition ranging from wound healing to cancer treatment. (Niranjan & Prakash, 2008)

Health benefits:

- Antibacterial activity
- Antiviral activity
- Antifungal activity
- Antitumor activity
- Antioxidant activity
- It cures inflammatory, hepatic any many problems.

Chemical Constituents:

- Carbohydrate
- Water
- Minerals
- Vitamins
- Niacin
- Calcium
- Copper
- Riboflavin
- Iron
- Magnesium
- Potassium
- Zinc
- Flavonoids
- Phenolic acid

Composition:

Table: 02 Composition of chemical constituents		
COMPONENT	PERCENTAGE	
Carbohydrates	82.4gm	
Fructose	38.5gm	
Glucose	31gm	
Sucrose	1gm	
Other sugar	11.7gm	
Dietary fiber	0.2gm	
Protein	0.3gm	
Water	17.1gm	
Riboflavin (vit. B12)	0.038mg	
Niacin (vit. B3)	0.121mg	
Pantothenic acid (vit. B5)	0.068mg	
Pyridoxine (vit. B6)	0.024mg	

Excipients considered for the formulation:

Table: 03 Excipients and their use in %		
Excipient name	% Use	
Croscarmellose sodium (super disintegrating agent)	0.5% to 2%	
Sodium CMC	0.5% to 2%	
Sodium starch glycolate (super disintegrating agent)	0.5% to 2%	
Cross povidone (super disintegrating agent)	0.5% to 2%	

For our formulation preparation we select all these disintegrating agents according to reduce disintegration time of our tablet with suitable proportion added of disintegrating agent in our mixture.

CROSS CARMELLOCE SODIUM



Figure: 09 Cross Carmellose Sodium

Nonproprietary name:

- BP Croscarmellose sodium
- JP Croscarmellose sodium
- PhEUR Croscarmellose sodium
- USP-NF Croscarmellose sodium

Synonym:

Cross linked carboxymethylcellulose sodium, primellose

Functional Category:

Tablet Disintegrant

The concentration of this disintegrating agent used in tablet (0.5%-5%) and in capsule (10%-25%). Croscarmellose sodium occur as an odorless, white or grayish white powder.

CROSSPOVIDONE

Nonproprietary name:

- BP Crosspovidone,
- PhEur Crosspovidone
- USP-NF Crosspovidone

Synonyms:

Crosslinked povidone, Kollidon CL-M

Functional Category:

Tablet disintegrant

Crosspovidone is a white to creamy white finely divided free flowing practically testless, odorless or nearly odourless hygroscopic powder.

SODIUM STARCH GLYCOLATE



Figure: 10 Sodium Starch Glycolate

Nonproprietary name:

- BP- Sodium starch glycolate
- Ph-Eur Sodium starch glycolate

USP-NF - Sodium starch glycolate

Synonyms:

Carboxy methyl starch, Sodium salt

Functional Category:

Tablet disintegrant

It is a white or almost white free flowing very hygroscopic powder.

SODIUM CMC (CARBOXYMETHYL CELLULOSE SODIUM)



Figure: 11 Sodium CMC (Carboxymethyl Cellulose Sodium)

Nonproprietary name:

- BP- Carmellose sodium
- JP- Carmellose sodium
- PhEur- Carmellose sodium
- USP- Carboxy methyl cellulose sodium

Synonyms:

Aqualon CMC, Akucell.

Functional Category:

Coating agent, stabilizing agent, suspending agent, Tablet and Capsule disintegrating agent, binder, viscosity-increasing agent, water absorbing agent. It is white to almost white, odourless, tasteless, granular powder. It is hygroscoping after drying.

METHODS

METHODOLOGY OF VATI:

Medicines prepared in the form of tablet or pills are known as Vati and Gutika. These are made of one or more drug of plant, animal or mineral origin.

Method of preparation:

The drugs of plant origin are dried and made into fine powders, separately. The minerals are made into Bhasma or Sindura, unless otherwise mentioned. In cases where Parada and Gandhaka are mentioned, kajjali is made first and other drugs are added, one by one, according to the formula. These are put into a khalva and ground to a soft paste with the prescribed fluids. When more than one liquid is mentioned for grinding, they are used in succession. When the mass is properly ground and is in a condition to be made into pills, Sugandha dravyas, like Kasturi, karpüra, which are included in the formula, are added and ground again. The criterion to determine the final stage of the formulation before making pills is that it should not stick to the fingers when rolled. Pills may be dried in shade or in sun as specified in the texts. In cases where sugar or jaggery (guda) is mentioned, Paka of these should be made on mild fire and removed from the oven. The powders of the ingredients are added to the Paka and briskly mixed. When still warm, vaṭakas should be rolled and dried in shade.

Characteristics and Prevention:

Pills made of plant drugs when kept in air tight containers can be used for two years. Pills containing minerals can be used for an indefinite period. Pills and Vatis should not lose their original color, smell, taste and form. When sugar, salt or kṣāra is an ingredient, the pills should be kept away from moisture.

METHODOLOGY OF TABLET:

Direct compression method for Tablet:

There are a few crystalline substances, such as sodium chloride, sodium bromide, and potassium chloride that may be compressed directly. The vast majority of medicinal agents are rarely so easy to tablet, however. In addition, the compression of a single substance may produce tablets that do not disintegrate. If disintegration is a problem, other components are needed, which in turn may interfere with the compressibility of the active ingredient and thus minimize the usefulness of the method. Most materials possess relatively weak intermolecular attraction or are covered with films of adsorbed gases that tend to hinder compaction. Thus, most large-dose drugs do not lend themselves to this process. With other drugs having small doses, uniform blends of the drug and coarser direct compression diluents cannot be achieved, which makes this process impractical. However, the use of compressible diluents with many moderate- dose drugs make this process the most streamlined method of tablet manufacture. A directly compressible diluent is an inert substance that may be compacted with little difficulty and may compress even when quantities of drugs are mixed with it. Compression capacity is still maintained when other tablet materials necessary for flow, disintegration, and so forth are blended in. Directly compressible excipients are examined in detail previously in this chapter Direct compression materials, in addition to possessing good flow and compressibility. A tablet is a hard, compressed medication in round, oval or square shape. For our tablet preparation we directly compress mixed powder without adding any sweetner, diluent, honey act as a binder for our formulation. We add super disintegrating agent and also normal disintegrating agent in our formulation. Used them in combination with each other with suitable necessary proportion as requires for our need.

Evaluation parameter:

1. Physical Evaluation:

The formulation's color and appearance were visually assessed. The consistent dispersion of extracts during the formulation process both touch and visual appearance were used to confirm this test. The texture, color, and smell of the Tablet were examined directly to determine its physical properties. All formulas produced products that were light reddish brown in color.

2. Disintegration test:

The USP device to test disintegration uses 6 glass tubes that are 3 inches long, open at the top, and held against a 10-mesh screen at - the bottom end of the basket rack assembly to test for disintegration time. One tablet is placed in each tube, and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid, or simulated intestinal fluid, at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$, such that the tablets remain 2.5 cm below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of the beaker. A standard motor-driven device is used to move the basket assembly containing the tablets up and down through of 5 to 6 cm at a frequency of 28 to distance be minute. Perforated plastic dishes may also the tablets and impart an abrasive action to in the test. These are placed 32 cycles the tablets. The discs may or may not be meaningful or impart more sensitivity to the test, but they are useful for tablets that float. (Bhat Scholar et al., 2019)



Figure no: 12 Disintegration Apparatus

3. Hardness test:

Tablet requires a certain amount of strength, or hardness and resistance to friability, to withstand mechanical shocks of handling in manufacture, packaging and shipping. Adequate tablet hardness and resistance to powdering and friability are necessary requisites for consumer acceptance. According to Indian pharmacopoeia of herbal

tablet is between 4 to 6. We use two hardness tester monsanto hardness tester and Pfizer hardness tester.



Figure no: 13 Pfizer Hardness Tester



Figure no: 14 Monsanto Hardness Tester

4. Friability test:

Tablet hardness is not an absolute indicator of strength since some formulations, when compressed into very hard tablets, tend to Cap" on attrition, losing their crown portions. Therefore, another measure of a tablet strength, its friability, is often measured. Tablets that tend to powder, chip, and fragment when handled lack elegance and consumer acceptance, and can create excessively dirty processes in such areas of manufacturing as coating and packaging. They can also add to a tablet's weight variation or content uniformity problems. The friability test is official in USP but not in BP and IP The laboratory friability tester is known as the Roche friabilator. This device subjects a number of tablets to the combined effects of abrasion and 1 shock by utilizing a transparent synthetic polymer chamber with an internal diameter between 283 and 291 mm and a depth between 36 and 40 mm that revolves at 25 +1 rpm. The tablets are tumbled from a distance of six inches at each turn of the drum by a curved - projection. Normally, a preweighed tablet sample is placed in the friabilator (w), which is then operated for 100 revolutions. For - tablets with a unit weight equal to or less than 650 mg, take a sample of whole tablets corresponding as near as possible to 6.5 g. For tablets with a unit weight of more than 650 - mg, take a sample of 10 whole tablets. After testing, the tablets are dusted and reweighed (wo) The friability, f, is given by: F = 100 * (1- W0/W)

Generally, the test is run once. If obviously cracked, cleaved, or broken tablets are present in the tablet sample after tumbling, the sample fails the test. If the results are difficult to - interpret or if the weight loss is greater than = the targeted value, the test should be repeated twice and the mean of the three tests determined. A maximum mean weight loss from s the three samples of not more than 1.0% generally considered acceptable for conventional compressed tablet.



Figure no: 15 Friability Testing Machine

BATCH HISTORY: VATI

For the beginning of the practical we start to formulate vati formulation. Vati is one type of ayurvedic formulation (tablet / pill) commonly available in market.

Used material:

- 1. Beet Root Powder
- 2. Amla Powder
- 3. Honey

Procedure:

First, we sieving of both powders using 120 mesh size sieves for collection of fine powder. Then we separate the coarse and fine powder. After this process we mix both fine powder of amla and beet root in equal amount and also add honey in suitable proportion, then mix it properly at the end of process we get vati of our result.

Batch-1:

Proportion of material:

Amla Powder- 10gm, Beet root powder- 10gm, Honey- 12ml.

Observation of first batch at the end of process vati formulate we found that the proportion of honey is too much so the vati became excessive sticky, vati generally should be non-sticky (ideal requirement for vati). So, we have to discard this batch.

Batch-2:

Proportion of material:

Amla powder- 1gm, Beet Root Powder- 1gm, Honey- 1.3ml

Observation of this batch at the end we found that vati formula is slightly better than batch-1 but for compare to ideal property is not satisfy so we have to further reduce the proportion of materials.

Batch-3:

Proportion of material:

Amla Powder- 1gm, Beet Root Powder- 1gm, Honey- 0.5ml

Observation of this batch the formulate vati matched our ideal property of vati, this batch is non sticky.

Evaluation:

Table: 04 Evaluation of Vati				
BATCH.NO	COLOUR	ODOUR	TASTE	STICKINESS
BATCH-1	Dark reddish Brown	Earthy	Bitter	Excessive Sticky
BATCH-2	Light Reddish Brown	Earthy	Bitter	Slightly Sticky
BATCH-3	Light Reddish Brown	Earthy	Slightly Bitter	Non-Sticky

BATCH HISTORY: TABLET

Used material:

- 1. Amla powder
- 2. Beet root powder
- 3. Honey

Procedure:

Here we used direct compression method, in this method both materials are taken in equal amount and mix together with honey.

- Weighing (equal weight of Amla and Beet root powder)
- Mixing (mix both powder with add sufficient amount of honey)
- Sieving (sieve of the powder in 120 mesh size sieve)
- Compression (compress powder in tablet punching machine)

Batch-1:

In this batch for prepare tablet we firstly take equal amount of amla and beet root powder (10gm) than add 2.5ml amount of honey drop wise, mix them properly for uniform mixing.

After the mixing of powder, we saw that honey is not uniformly mixed with both powder it mixed with minor proportion major powder is not mix with honey so batch is discarded.

Batch-2:

In this batch for tablet prepare we follow same procedure for prepare mixed powder, but this time we try more properly mixed both powder and honey in trituration bath and at the we get effectively mixed powder compare to batch-1. That mixed powder further pass through 120 mesh size sieve for remove large particles of mixed portion, collect fine powder. The fine powder we used for tablet with direct compression method. In starting we used small cavity for tablet to identify the powder is able to give tablet, but when we start to process of make tablet, we face chopping of machine due to unequal mixing of powder and also the sometime the tablet is formed but it breaks due to low hardness.

Observation:

Powder is still unequal mixed proportion of honey. Chopping issue occur due to honey. Lower hardness of tablet, easily break down.

Batch-3:

Due to facing mixing issue of powder with honey in previous batches, we solved that issue by using geometric dilution method of mixing.

Geometric Dilution: By this method the drug is placed with an approximately equal volume of the diluent in mortar and is mixed thoroughly by trituration. Then second portion of diluent equal in volume to the mixture is added and the trituration repeated.

Process For 12 gm:

STEP-1: first we accurately weight 1gm of mixed powder and 1ml of honey in mortar pestle, thoroughly mixed properly. (total weight of mixture is 2gm).

STEP-2: Now we take equal amount of mixed powder in mortar pestle, take 2gm of mixed powder (Amla powder + Beet root powder) add in mortar pestle, mixed them thoroughly for equal amount of mixing of powder with honey. (total weight 4gm)

STEP-3: We have to take 4gm of mixed powder in mortar pestle, mixed all material in mortar pestle properly. (total weight is 8gm).

STEP-4: Now we don't have equal amount of mixed powder so we have added remaining mixed powder in mortar pestle and mixed them thoroughly.

Now we have homogenous mixing of both powder with honey and this powder is pass through the sieve 120 mesh size for collect fine powder of equal mixing. After that process we start for make tablet.

Observation:

Proportion of honey is evenly distributed in mixed powder. Chopping issue due to excessive honey is solved. Tablet is made without any problems. Error is occurred related to hardness. (ideal hardness is between 4 to 6), but our tablet hardness lies between lower. With using small cavity size. Also perform disintegration and our tablet disintegrate

completely within 7 minutes (ideal time for disintegration of normal tablet is 15 minutes). Hardness of tablet of this batch is 4.

Batch-4:

In this batch is formed for the purpose for the decrease the disintegration time using disintegrating agent. Used disintegrating agent = croscarmellose sodium (super disintegrating agent). Ideally disintegrating agent is used in any tablet formation range is 0.5% to 2%. So accordingly, we used 2% proportion of croscarmellose sodium of total weight of powder. So, we use 0.24gm(240mg) in our tablet preparation.

Process For 12 gm:

STEP-1: First, we accurately weight 1gm of mixed powder and 1ml of honey in mortar pestle, thoroughly mixed properly. (total weight of mixture is 2gm).

STEP-2: Now we take equal amount of mixed powder in mortar pestle, take 2gm of mixed powder (Amla powder + Beet root powder) add in mortar pestle, mixed them thoroughly for equal amount of mixing of powder with honey. (total weight 4gm)

STEP-3: We have to take 4gm of mixed powder in mortar pestle, mixed all material in mortar pestle properly. (total weight is 8gm).

STEP-4 – now we don't have equal amount of mixed powder so we have added remaining mixed powder in mortar pestle and mixed them thoroughly. Now we have homogenous mixing of both powder with honey, now this powder is pass through the sieve 120 mesh size for collect fine powder of equal mixing. After that we add 0.24 gm (240mg) of super disintegrating agent in it mixed properly.

Observation:

This batch is mainly comparing the disintegrating time of our tablet with previous batch which perform without add disintegrating agent. Time is obtained after perform disintegration test is 5 minutes. Hardness of tablet of this batch is 5.

Batch-5:

The purpose for perform another batch is we want to reduce disintegration time so this time we add two super disintegrating agents in equal proportion. Used disintegrating agent is croscarmellose sodium and sodium starch glycolate. Both are used in proportion of 1% of total weight of mixed powder. Take 0.12gm (120mg) of each disintegrating agent add in to the mixed powder. Same process follows as previous for make uniformed mixed powder.

Observation:

This batch takes 4.30minutes disintegration time compare to previous batch its good. Hardness of this batch is 5.

Batch-6:

In this batch, we replace one super disintegrating agent (sodium starch glycolate) with normal disintegrating agent (carboxymethylcellulose sodium) to reduce disintegrating time. Both are used in proportion of 1% of total weight of mixed powder. Take 0.12 gm (120mg) of each disintegrating agent add in the mixed powder.

Observation:

This batch takes 4.8 minutes of disintegration time compare to previous batch.

Batch-7:

In this batch, we change die cavity size to change tablet size.

Observation:

It causes chopping issue of powder, so we reduce hardness of tablet.

Batch-8:

In this batch, we only add sodium starch glycolate as super disintegrating agent. We used 2% proportion of sodium starch glycolate (super disintegrating agent) We take 0.24gm(240mg) in our tablet.

Observation:

This batch takes 6 minutes of disintegration time compare to previous batch.

Batch-9:

In this batch we only add carboxymethylcellulose as disintegrating agent. We used 2% proportion of carboxymethylcellulose (disintegrating agent). We take 0.24(240mg) in or tablet.

Observation:

This batch takes 6 to 7 minutes of disintegration time compare to previous batch.

Batch-10:

In this batch we add one more herbal ingredient curcumin because curcumin also give good effect for the blood purifier and in some limit 100 to 500 mg in single dose so in this batch, we add 1 gm curcumin in 5.38 gm mixed amla and beet root powder equal proportion with honey 1 ml. This batch is prepared for 10 tablets the final appearance of the powder is dull yellow color also we add 1-1 % of super disintegrating agent croscarmellose sodium and sodium starch glycolate. After punching the tablet used tablet punching machine.

Observation:

Disintegration time for this tablet is 8.48 minutes. The hardness of this tablets is 4.

EVALUATION:

Table: 05 Evaluation of Tablets				
BATCH-	COLOUR	ODOUR	HARDNESS	DISINTEGRATION
NO.				TIME
Batch-1	Dark reddish brown	Earthy	-	-
Batch-2	Dark reddish brown	Earthy	-	-
Batch-3	Light reddish	Earthy	4	7 minute
	brown			
Batch-4	Light reddish	Earthy	5	5 minute
	brown			

Batch-5	Light reddish brown	Earthy	5	4.30 minute
Batch – 6	Light reddish brown	Earthy	5	4.8 minutes
Batch - 7	Light reddish brown	Earthy	No observation due to chopping issue	-
Batch – 8	Light reddish brown	Earthy	5	6 minutes
Batch – 9	Light reddish brown	Earthy	5	6 minutes
Batch- 10	Dull yellow	Smell like curcumin	4	8.48 minutes

WEIGHT VARIATION TEST:

SR.	WEIGHT OF	DEVIATION	DEVIATION
NO.	TABLET (mg)	(mg)	(%)
1.	600	-8.75	1.46
2.	600	-8.75	1.46
3.	595	-3.75	0.625
4.	590	1.25	0.20
5.	593	-1.75	0.29
6.	593	-1.75	0.29
7.	595	-3.75	0.625
8.	583	8.25	1.37
9.	585	6.25	1.04
10.	580	11.25	1.87
11.	600	-8.75	1.45
12.	585	6.25	1.04
13.	587	4.25	0.71
14.	580	11.25	1.87
15.	582	9.25	1.54
16.	587	4.25	0.72
17.	600	-8.75	1.45
18.	600	-8.75	1.45
19.	595	-3.75	0.625
20.	595	-3.75	0.625

Average weight of all tablet is 591.25 deviation of tablet is not more than 5%, so weight variation test is passed.

RESULT AND DISCUSSION:

TABLE: 06 Result			
SR.NO	PARAMETER	RESULT	
1.	Colour	Yellow	
2.	Odour	Earthy mustard like aroma	
3.	Taste	Slightly bitter	
4.	Shape	Round	
5.	Hardness(kg)	5	
6.	Disintegration time(minutes)	8.48 minutes	



Figure no: 16 Blood purifier tablets

CONCLUSION:

Which is selected and identified herb has individually proven blood purification test and it is from herbal background so it has no side effect and also makes sustainable formulation for environmental. This formulation has been pharmaceutically evaluated and it gives good formulation characteristics. If it is evaluated for the clinical study because of its herbal nature. As we are trying to purify the blood and thus it will improve skin health from the root itself. We are trying to cure chronic skin diseases from its root and this herb has been proved to give the best blood purification effect. Improve this formulation may prove better for the chronic skin health diseases.

FUTURE PROSPECTS:

Bioavailability of curcumin can be enhanced.

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