

FORMULATION AND EVALUATION OF DUAL ACTING HERBAL TABLET CONTAINING TURMERIC AND CAFFEINE

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ABSTRACT

The formulation aimed to synergize the benefits of both turmeric and caffeine in a single tablet and targeting condition on inflammation, pain. Osteoarthritis is a chronic joint disease where cartilage wears down, leading to bone-on-bone contact, pain, limited mobility, stiffness. Turmeric and caffeine have anti-inflammatory and analgesic properties by combination it helps in osteoarthritis. Turmeric is rich in curcumin it exhibits potent anti-inflammatory and also analgesic properties, while caffeine enhance pain relief and serves as a stimulant also improve mental alertness, focus and increase the curcumin bioavailability. Combination of these natural ingredient into a single tablet could provide a synergistic effect and improving efficacy and patient compliance.

The combination significantly reduce pain and improve joint function in osteoarthritis patients the dual action formulation exhibited potential effects for conditions such as chronic inflammation and cognitive decline. The turmeric and caffeine tablet presents a combined therapeutics effects in a single dosage form for osteoarthritis offering both symptomatic relief and potential long term benefits in managing the osteoarthritis condition the tablet was designed a direct compression method to obtained a optimal bioavailability.

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INTRODUCTION

Herbal formulation is a dosage form consists of one or more herbs in particular quantities to give nutritional, cosmetic benefits and to treat alleviate disease of human beings or animals. Herbal formulation contains a herbal substance or in combination of one or more herbal substance to process like extraction, distillation, fractionation, fermentation include powder. Polyherbal formulation are use of more than one herb in a therapeutic preparation like with any drug concerning herbs' benefits, scant drawbacks have to do with their use and hold the potential to pose danger to other mild or even severe medical complications primarily liver toxicity. All too often, many adverse events involving herbal medicines go undisclosed many times. The rational explanation behind these adverse medical conditions with herbs/their preparations can be attributed to the existence of unprocessed / non-branded herbal products contaminating with hazardous materials end

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substandard product quality, adulteration or substitution, herb-drug contraindications, presence of inherently toxic compounds and anti nutritional factors. Furthermore, a lack of awareness about the frequency and period of consumption of herbal Like with any drug concerning herbs' benefits, scant drawbacks have to do with their use and hold the potential to pose danger to other mild or even severe medical complications primarily liver toxicity. All too often, many adverse events involving herbal medicines go undisclosed many times. The rational explanation behind these adverse medical conditions with herbs/their preparations can be attributed to the existence of unprocessed / non-branded herbal products contaminating with hazardous materials end substandard product quality, adulteration or substitution, herb-drug contraindications, presence of inherently toxic compounds and anti-nutritional factors. Furthermore, a lack of awareness about the frequency and period of consumption of herbal supplements by self-medicating individuals or unqualified practitioners has resulted in additional noise over health issues. Thus, processing standardization, and characterization of herbal products are essential for purity, identification, and quality control of herbal for the production of a more uniform product. In this regard, the WHO has standardized procedures and techniques for standardization of herbal medications. Although

traditional methods mentioned in the WHO document still exist, new techniques include barcoding, protein chip, metabolomics, genomics fingerprinting, analytical examination of compounds, spectroscopy among others, which have found their way in the previous decades for the standardization of herbs/herbal product.[1]

Types of Herbal Formulation

Herbal Tablet

Tablet made from plant, herbs, natural ingredients to promote health and wellness. Use of herbal is independent of any age group they almost has no side effect and effective remedies. Solid dosage form are most popular drug delivery system like tablet and capsule they have high patient compliance, easy to market, easy to produce and also have good physical and chemical stability [2,3].

Direct compression is a formulation technique in which tablets are compressed directly from the mixture of the drug and the excipient without preliminary treatment [4,5]. The direct compression formulation is simple including an (API), a diluent, a lubricant, and a disintegrant [6]

Herbal medicine or botanical medicine, phytotherapy or phytomedicine, is the art and science of using plant extracts, tinctures, and infusions as medicines for the prevention and treatment of ailments. The use of herbal medicine dates back thousands of years, practiced by different cultures in ancient China, Egypt, Greece, and Rome. [7]

The philosophy behind herbal medicine is holistic approach—treating the whole man from the physical, to emotional, and spiritual in opposition to the symptoms [8]; plant-based remedies have unique healing qualities that allow them to create balance and facilitate recovery through self-healing powers; this is different from conventional practices since they focus on chemicals in the form of prescription medicines and surgery.[9]

Some benefits that herbal medicine offers include that it is natural and safe, if used appropriately. This remedy is cost-effective and holistic. Herbal remedies work by enhancing wellness, preventing illness from arising. They offer alternative remedies for patient's intolerant to pharmaceuticals or requiring additional complementary therapies.

Benefits of Herbal tablet

Natural Ingredients They contain plant-based components that are often thought to be more in tune with how the body works than man-made drugs. It has fewer side effects. There are many herbal tablet users who claim to experience very few side effects coming their way as compared with pharmaceutical drugs, although different by person and herb at play.[10]

Holistic approach Most herbal remedies focus not on symptoms but on taking care of the overall general state of well-being in their patients. As a complement it is often used as an addition to traditional treatments for the enhancement of overall health and long term-wellness.[11]

A lot of herbal tablets are available in the market that cater to the need for stress relief to digestive health. There are also herbs that specifically target specific conditions such as

anxiety, inflammation, or immune health.[12]

Mechanism of Herbal tablet

Herbal tablets have curative properties due to various mechanisms, like antioxidant activity, modulation of cell signaling, modulation of the immune system, inhibition of enzymes, regulation of hormones, and regulation of neurotransmitters [13]. Alkaloids, flavonoids, terpenes, glycosides, and saponins are main phytoconstituents responsible for these effects. Upon administration, absorption of herbal extracts occurs across the gut, skin, and mucous membranes, distribute it to all parts, metabolize it in the liver, and excreted through urine, stool, or sweat [14]. Antioxidant activity prevents the action of free radicals and decreases oxidative stress and inflammation. Modulation of cell signaling influences gene expressions and protein synthesis, modulation of the immune system prohibits infections and autoimmune diseases [15]. Inhibition of an enzyme and regulation of a hormone alleviate various diseases resulting from endocrine disorders. [16]

Marketed herbal formulation

Sr.No	Product	ingredients	indication	Reference
1	Turmeric tablet	Curcuma Longa	Joint Pain	17
2	Ginger Tablet	Zingiber	Digestive issue	18
3	Ginkgo Biloba	Ginko biloba	Cognitive Function	19
4	Tulsi Syrup	Ocimum sanctum	Respiratory issues	20
5	Ashwagandha syrup	Withania Somnifera	Stress Relief	21
6	Valerian Emulsion	Valeriana officinalis	sleep support	22
7	Ginger Capsule	Zingiber officinale	Digestive issue	23
8	Turmeric Curcumin	Curcumin Longa	Joint Pain	24
9	Omega-3 Softgel	Fishoil	Heart Health	25
10	CoQ 10 Soft Gel	Ubiquinone	Energy Production	26
11	Grape Seed Softgel	Vitis Venifera	Anti-oxidant Support	27
12	Neem Face Mask	Neem, Tulsi	Acne control	28
13	Aleo vera Emulsion	Aleo vera, Vitamin E	Hydrating	29
14	Neem Cream	Neem, tulsi, Aloe vera	Acne Control	30

Herbal drugs

Herbal drugs or phytomedicines are drug products prepared from plants, algae, and fungi for the treatment and prevention of various health disorders [31]. These products contain bioactive compounds like alkaloids, glycosides, and terpenes that show therapeutic effects. Herbal drugs can be classified as, Crude herbal drugs, Unprocessed plant materials (for example, dried leaves, roots). Herbal extracts: Concentrated preparations of bioactive

compounds (for example, tinctures, capsules). Herbal teas: Infusions of plant materials in hot water (for example, peppermint tea). Herbal drugs have been used for many centuries in traditional medicine systems like Ayurveda, Unani, and Traditional Chinese Medicine (TCM). The efficacy of many herbal drugs including, for cognitive enhancement (Ginkgo biloba) [32], for mild depression St. John's Wort for mild depression.[33]

Turmeric



It is an herbal medicine used for various conditions such as to reduce inflammation and oxidative stress, and support skin and wound healing. It has also been traditionally used to alleviate respiratory issues such as bronchitis and asthma, and to relieve joint pain, abdominal pain, fever, wrinkle skin, diabetic wounds, antihelminthic, anemia, cough and also many other diseases [34,35].

Genus - *Curcuma*

Synonym - Indian Saffron, Turmeric, Haldi,

Haridra

Biological Source - Turmeric consists of dried as well as fresh "Rhizome" of the plant *Curcuma longa*

1. Family - Zingiberaceae
2. Geographical - It is grown on a large scale in India, China, East India and Pakistan
3. Chemical constituents –
 - Alkaloids-Curculigoside and Curcuminol.
 - Glycosides: Curcumin glucoside and demethoxycurcumin glucoside.
 - Flavonoids-Quercetin, kaempferol, and isorhamnetin
 - Phenolic Acids-Caffeic, ferulic, and sinapic acids
 - Terpenes-Beta-pinene, beta-caryophyllene, and alpha-phellandrene

Properties

Turmeric's anti-inflammatory properties help alleviate joint pain, arthritis, and other inflammatory conditions.

Its antimicrobial and antiseptic qualities make it effective against wounds, skin conditions, and digestive issues. Turmeric also demonstrates anti-cancer properties, inhibiting tumor growth and preventing cancer cell proliferation[36]. Additionally, its neuroprotective effects may aid in preventing or managing neurodegenerative diseases like Alzheimer's and Parkinson's.

Turmeric's cardiovascular benefits include improving blood lipid profiles, preventing blood clots, and reducing blood pressure.

Its digestive benefits include alleviating symptoms of IBS, ulcerative colitis, and other gastrointestinal disorders. Overall, turmeric's diverse properties make it a valuable spice for promoting overall health and well-being

Direction for uses/dosage [37]

Curcumin, the active compound in turmeric, requires careful consideration for optimal benefits. Typical dosages range from around- 500 to 2000 mg per day. For joint pain and inflammation, 1000-2000 mg per day. While digestive issues, cognitive support, and antioxidant benefits may require 500-1000 mg per day.

Caution

- Allergic reactions: Monitor for signs of allergy.
- Surgery: Stop using turmeric 2 weeks before surgery.
- Autoimmune disorders: Consult a healthcare professional.
- Organ transplant recipients: Consult a healthcare professional.
- Severe liver or kidney disease: Avoid turmeric

Anti-inflammatory effect of Curcumin

Curcumin is a bioactive polyphenol derived from the plant *Curcuma longa*. This was used for several thousand years in traditional Indian and Middle Eastern medicine. The chemical structure of curcumin is (1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione). It is for this structure that curcumin derives its potent anti-inflammatory, antioxidant, anticancer, and neuroprotective activities. Curcumin exerts its activity through inhibiting pro-inflammatory enzymes and cytokines and scavenging free radicals; oxidative stress is also curtailed. Thus, it works against arthritis, cancer, and neurodegenerative diseases[38]. The bioavailability of curcumin, however, is not that good and gets improved with enhancers such as piperine (black pepper) [39,40]. Curcumin, a polyphenol extracted from turmeric, has potent anti-inflammatory properties, supported by numerous studies:[41,42]

Mechanisms of curcumin

NF- κ B (Nuclear Factor kappa B) NF- κ B is a transcription factor that regulates the expression of pro-inflammatory genes. Curcumin binds to the p65 subunit of NF- κ B. This binding inhibits NF- κ B's ability to translocate to the nucleus. As a result, NF- κ B cannot induce the transcription of pro-inflammatory genes.[43,44]

Pharmacological effect of curcumin

Curcumin decreases inflammation in rat model of arthritis - Rats with adjuvant-induced arthritis were administered curcumin orally at doses of 50, 100, or 200 mg/kg. Curcumin significantly decreased paw swelling, joint inflammation, and oxidative stress.[45] Curcumin pretreatment of rats at the dose of 50, 100, or 200 mg/kg significantly improved survival rate before lipopolysaccharide (LPS) challenge. Curcumin reduced TNF- α , IL-1 β , and IL-6 levels. Curcumin, administered orally at 50, 100, or 200 mg/kg, reduced inflammation, oxidative stress, and improved colon histology in rats with dextran sulfate sodium-induced colitis.[46]

Caffeine



It is Worldwide most consumed by adolescents because it is present in most popular coffee and tea which help to maintain the mental as well as physical health .It is bitter in taste ,white crystalline alkaloid structurally identified as 1,3,7 -trimethylxanthine it occurs naturally tea leaves ,kola nuts and cocoa beans [47] . Caffeine is natural chemical stimulant and belong to class of compound methylxanthines and antioxidant [48] Moderate caffeine consumption, defined as up to 400mg per day for healthy adults, may have health benefits, including neuroprotection, cardiovascular health, and anti-inflammatory effects .

The more intake of caffeine can cause sleep complication and negatively affect daytime performance [49] Common food and beverage sources of caffeine include coffee (95-200mg per 8oz cup), tea (20-90mg per 8oz cup), chocolate (6-12mg per 1oz), energy drinks (50-160mg per 8oz).[50]

Biological sources - Coffea arabica , Coffea canephora

Family -Theaceae

Physical Appearance

White crystalline powder

Odor: Characteristic, bitter

Taste: Bitter

Soluble in water, ethanol and chloroform

M.P.: 227-228°C

Caffeine is mostly applied as follows

1. Beverage (coffee, tea and energy drinks)
2. Pharmaceuticals (stimulants, analgesics)
3. Cosmetics (skin, hair care)
4. Food industries, flavoring and preservative

Properties

- Relieves tension headaches, migraines, and menstrual cramps
- Reduces chronic pain, fibromyalgia, and arthritis symptoms
- Enhances post-operative pain management
- Improves exercise-induced pain tolerance
- Relieves tension headaches, migraines, and menstrual cramps
- Reduces chronic pain, fibromyalgia, and arthritis symptoms
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- Improves exercise-induced pain tolerance

Caution

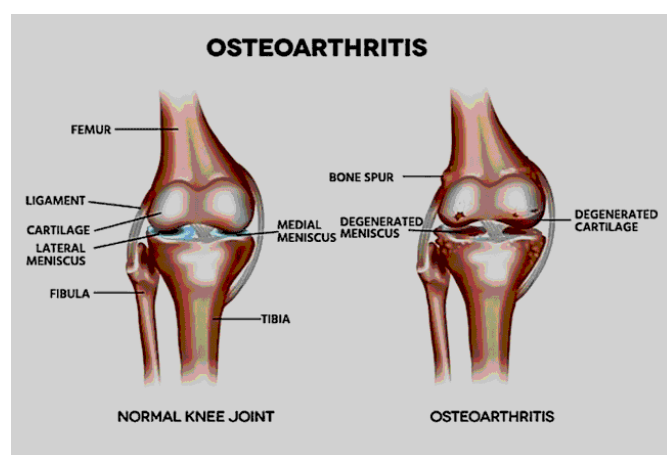
Pregnancy and breastfeeding: limit caffeine to 200mg/day or less.

- Children and adolescents: try to avoid or limit caffeine intake.
- Anxiety disorders: caffeine may exacerbate symptoms.
- High blood pressure: monitor blood pressure.
- Heart conditions: consult a healthcare professional.
- Sleep disorders: avoid caffeine before bedtime.

Analgesic effect of caffeine

caffeine exerts its analgesic effects through multiple mechanisms. Primarily, it blocks adenosine receptors, specifically A1 and A2A subtypes [51], which reduces pain transmission by decreasing the activity of nociceptive neurons [52]. Additionally, caffeine increases the release of dopamine and endorphins, natural painkillers that activate reward pathways and reduce pain perception [53]. Caffeine also enhances descending pain inhibition pathways, activating the release of neurotransmitters such as serotonin and norepinephrine , which further contribute to pain reduction. [54]

Osteoarthritis



Osteoarthritis (OA) is a degenerative joint disease characterized by progressive wear and tear of the joint cartilage and underlying bone. It's the most common type of arthritis and a leading cause of disability worldwide

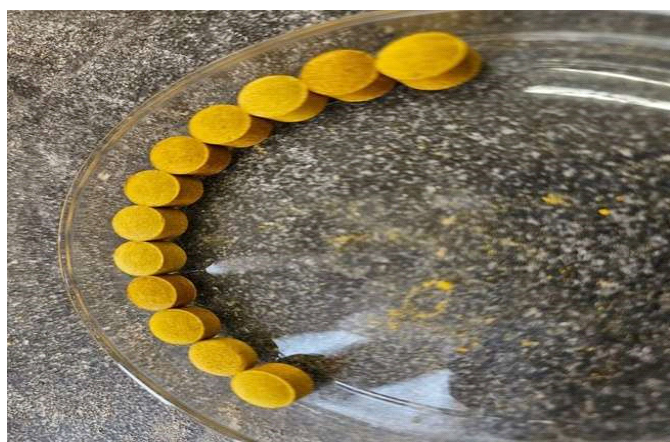
OA is the most common type of arthritis and can affect various joints, including knees, hips, hands, spine, feet, and ankles, impacting daily activities and overall quality of life.

Symptoms :- include joint pain and stiffness, especially after rest, limited mobility and flexibility, swelling, redness, and warmth around the joint, and clicking or grinding sounds when moving the joint.

Curcumin, a polyphenol extracted from turmeric, exhibits potent anti-osteoarthritic properties. It reduces joint pain and inflammation, improves joint mobility and flexibility, inhibits cartilage degradation, and enhances chondrocyte viability and function [55]. Curcumin's mechanisms include inhibition of NF- κ B and inflammatory cytokines, antioxidant activity, modulation of matrix metalloproteinases (MMPs) and aggrecanases, and stimulation of collagen synthesis and tissue repair [56]. Human studies demonstrate that curcumin supplementation (1,000-2,000 mg/day) alleviates osteoarthritis symptoms, improves joint mobility, and reduces pain and inflammation [57]

Caffeine inhibits adenosine receptors, reducing inflammation and pain transmission. Additionally, caffeine's antioxidant activity mitigates oxidative stress, a key contributor to OA progression [58]. Human studies have shown that moderate caffeine consumption (200-400 mg/day) improves joint mobility, reduces pain and stiffness, and enhances quality of life in OA patients [59]. Animal studies support these findings, demonstrating that caffeine supplementation reduces joint inflammation and cartilage degradation in OA models [60]

Purpose of tablet



- Anti-inflammatory
- Pain relief
- osteoarthritis

MATERIAL AND METHODS

Material Used in Preparation – curcumin from turmeric, caffeine from tea leaves, starch, talc, lactose, gum Acasia

Equipment Used – Electric Weighing Balance, Sieves, hot air oven, Vernier caliper, USP Type [tablet dissolution apparatus], Tablet compression machine, hardness tester (Monsanto, India), Bulk density apparatus, Dissolution Apparatus, Friability apparatus

Method

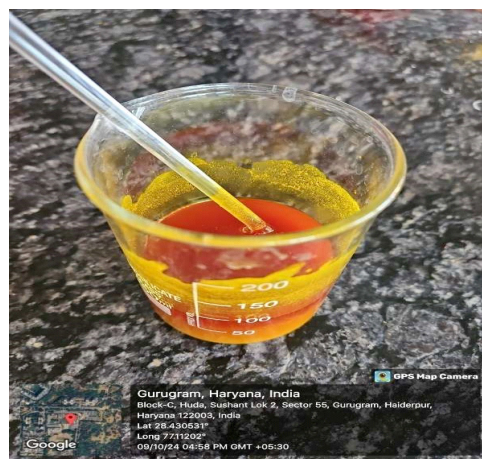
3.1. Plant Material Collection and Preparation turmeric and tea leaves were collected from a local market. Turmeric rhizomes and tea leaves were thoroughly washed with distilled water to remove any dirt or debris, and then dried in the shade at room temperature (25-30°C) for 2 to 3 days. The dried turmeric were

then ground into a fine powder using a laboratory grinder and stored in an airtight container at 4°C until further use

(extraction of curcumin from the turmeric by maceration extraction) [61]

Raw Material – Fresh or dried turmeric roots

1. Milling- Fine powder of turmeric powder
2. Solvent- ethanol is the preferred organic solvent [62]
3. Ration-1:5 to 1:10 (turmeric powder : solvent
4. Maceration –Turmeric powder in solvent; steep for 2 -14 days
5. Filtration - Filtration of mixture through a filter paper
6. Evaporation – Removal of solvents using heat
7. Crystallization – Collect curcumin – rich extract



Extraction of caffeine (liquid -liquid extraction) [63]

About 20 gm of tea is taken in a 500ml beaker.

- Add 90 ml of distilled water in the beaker & boil 30 minutes while stirring occasionally.
- Take filtrate in a separating funnel and add 20 ml chloroform.
- Shake vigorously so that total caffeine will be transferred to chloroform & separate the chloroform layer.
- Evaporate chloroform over a water bath.
- White caffeine crystals will be collected from the bottom



Formulation

Sr. No	Ingredients	Formulation 1	Formulation 2	Formulation 3
1	Curcumin (Extract)	2gm	3gm	4gm
2	Caffeine	1.5gm	1.5gm	1.5gm
3	Starch	0.5gm	0.7gm	0.6gm
4	Lactose	0.7gm	0.2gm	0.3gm
5	Talc	0.3gm	0.gm	0.6gm
Total		5gm	6gm	7gm

Pre-formulation

1. Calculation of Bulk density

Mass of powder per unit time

10gm of powder was filled in 50 ml cylinder and recorded the unsettled volume and by using the bulk density formula

$$\begin{aligned} \text{Bulk Density} &= \text{Mass/Volume} \\ &= 100\text{g}/50\text{ml} \\ &= 2\text{g/ml} \end{aligned}$$

2. Calculation of tapped density

Mass of powder per unit volume to remove air voids

10gm of sample was filled in 50 ml of cylinder and mechanically tapping 100 time cylinder by the use of tester of tapped density

Tapped density = M/V_f (M= mass , V_f = volume of tapped density)

3. calculation of Carr's Compressibility index

It measure the compressibility of powder by the use of tapped density and bulk density

$$\text{Carr's compressibility index} = \frac{\text{Bulk density} \times 100}{\text{Tapped density}}$$

4. Calculation of Hausner's ratio [64]

The measure of powder flowability and compressibility

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Flowability	Hausner's Ratio
Excellent	1.0 – 1.11
Good	1.11 – 1.18
Fair	1.18 – 1.25
Poor flow	1.35 – 1.45
Very poor flow	1.45 – 1.59

5. Calculation of angle of repose

The maximum possible angle between the surface of powder and the horizontal plane

It measure by the formula , $\tan \theta = h/r$ (height of powder , r= radius of the powder)

Flowability	Angle of Repose (Degree)
Excellent	25-30

Good	>35
Fair	35-40
Poor	43-55
Very poor	50-35

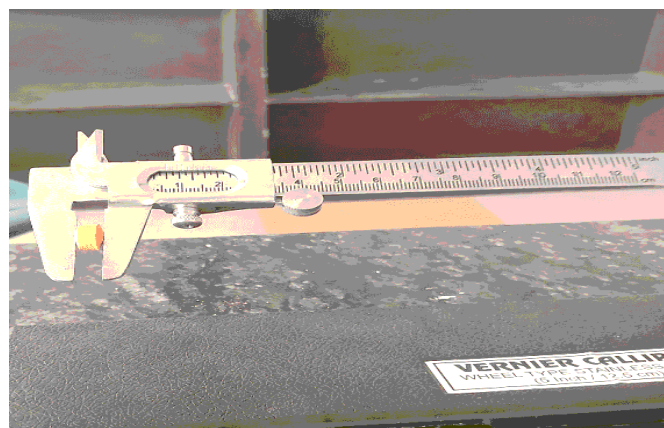
PROCEDURE

- Curcumin extract & Caffeine and other excipient was weighed, ground, and separately run and passed through 80-number sieve
- All materials other than talc and starch were combined and ground in a pestle and mortar
- pass through sieve number 80.
- Lumps was created After the combination of extract with Starch
- Lump was passed over sieve number 18 to obtain granules, dried in oven dryer at 35°C.
- Talc and starch was added
- Before placing in the desiccator once passed through Sieve no 18 to eliminate larger granules
- Compressed the granules into the desired punching machine for proper size and shape.

Evaluation

1. Thickness and diameter

Randomly 10 tablet are selected from each batch by the use of Vernier caliper can be determined the thickness and diameter of tablet and its average value was calculated[65]



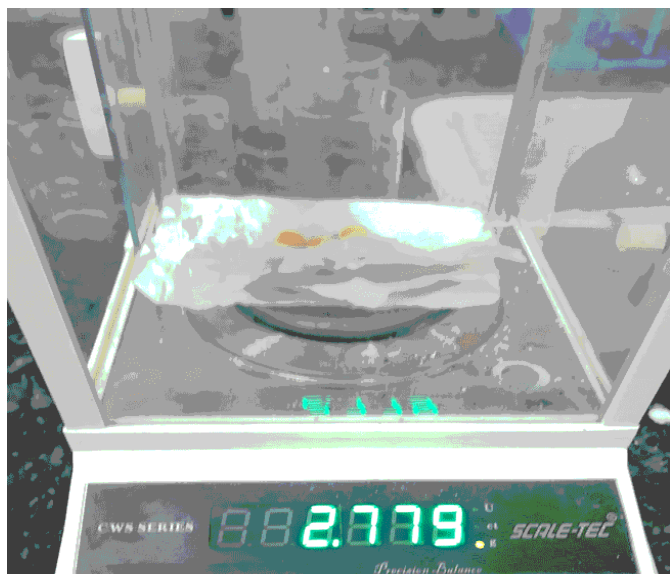
2. Organoleptic Properties

The physical characteristics of a tablet that affect our senses are

- Sight (color, shape)
- Touch (textur)
- Smell (odor)

3. Weight variation

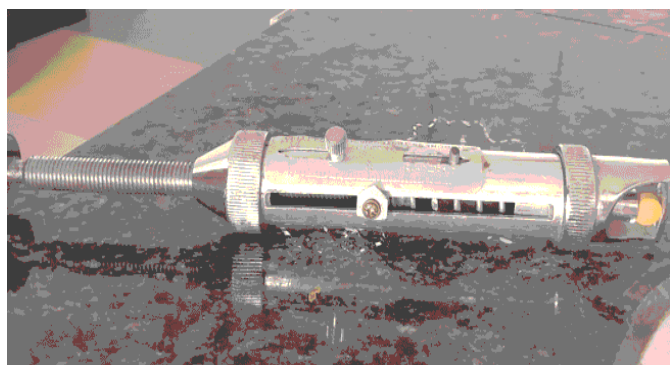
Randomly 20 tablet are picked up and weighed the individual weight and their average weight was measured than calculated and determine [66]



4. Hardness test

It can be determine by using Monsanto hardness tester

The pressure require to break the tablet Put the tablet between the jaw of the hardness tester and increase the pressure till the tablet break .



5. Friability

It was determine by using Roche Friabilator

Weigh and place the 20-30 tablet in friabilator and revolve friabilator (100 -200 revolutions) again weigh the tablet and calculate weight l



RESULT AND DISCUSSION

The powder blend was prepared by wet granulation method. The formulated formulation of pre -formulation results was having the good flow properties and compressibility. After the compression of the tablets by various physical parameter they are evaluated. Thickness and diameter of all the batch were within the range. The strength of the tablet within the range without breaking it was confirmed was by friability and hardness test .Weight variation test of all formulation results showed within the range.

Pre Formulation Parameter Results

Formulation	Angle Of Repose	Bulk Density	Tapped Density	Compressibility Index	Hausner's Ratio
F1	21.84 +- 1.23	0.64 +- 0.002	0.50+- 0.1	21.42 +- 1.67	0.83 +- 0.008
F2	24.83+-0.71	0.62 +- 0.004	0.51 – 0.009	19.69 +- 1.42	0.91 +- 0.008
F3	24.9 +- 0.32	0.62 +- 0.012	0.52 +- 0.003	18.68 +- 1.20	0.84 +- 0.026

Evaluation parameter

Formulation	Diameter	Thickness	Hardness	Friability	Weight Variation
F1	4.33+-0.001	7.21+-0.001	4.32+-0.16	4.42 +- 0.16	246.22 +- 0.96
F2	4.557+-0.002	7.62+-0.002	4.42+-0.23	4.42+-0.23	246.19 +- 0.52
F3	4.63+-0.003	7.668+-0.003	4.44+-0.32	4.44+-0.32	246.20 +- 0.83

Organoleptic Properties

1. **Sight :- a.) Colour - yellow**
b.) Shape – Round Biconvex
2. **Touch :- Texture – Smooth**
3. **Smell :- Odour- Earthy & Spicy**

CONCLUSION

The formulation of a dual-acting herbal tablet containing turmeric and caffeine presents a promising therapeutic approach for managing osteoarthritis and related conditions. Turmeric, rich in curcumin, demonstrates potent anti-inflammatory and analgesic properties, while caffeine enhances pain relief, acts as a stimulant, and improves the bioavailability of curcumin. The synergistic combination of these natural ingredients addresses the multifaceted challenges of osteoarthritis by reducing pain, enhancing joint function, and providing potential long-term benefits.

The tablet, formulated using the direct compression method, ensures optimal bioavailability and patient compliance. Preliminary studies suggest that this combination significantly reduces pain and improves joint function in osteoarthritis patients, with additional benefits for conditions such as chronic inflammation and cognitive decline. The careful consideration of dosage and potential side effects ensures the safe and effective use of this dual-acting tablet.

In conclusion, the turmeric and caffeine tablet offer a holistic, cost-effective, and user-friendly approach to managing osteoarthritis and related symptoms, potentially improving the quality of life for patients suffering from this debilitating condition. Further clinical studies are warranted to fully elucidate the long-term benefits and potential applications of this innovative formulation.

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