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EVALUATION OF POLYHERBAL FORMULATION

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ABSTRACT

The study is designed as evaluation of poly herbal formulation as combination tablet of Andrographis paniculata & Tinosporia cordifolia powders for the management of Diabetes mellitus and Hypertension (lowering blood pressure).

KEYWORDS: Poly herbal formulation. Andrographis paniculata, Tinosporia cordifolia, Diabetes mellitus, Hypertension.

INTRODUCTION

A tablet is a pharmaceutical dosage form. It comprises active substances and usually in powder pressed compacted into solid. The excipients can include binders, glidants and lubricants to ensure efficient tableting; disintegrants to promote tablet break-up in the digestive tract; sweeteners or flavors to enhance taste; and pigments to make the tablets visually attractive. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or to enhance the tablets appearance.

The compressed tablet is the most popular dosage form in use today. About two-thirds of all prescriptions are dispensed as solid dosage forms, and half of these are compressed tablets. A tablet can be formulated to deliver an accurate dosage to a specific site; it is usually taken orally, but can be administered sublingually, rectally or intra vaginally. The tablet is just one of the many forms that an oral drug can take such as syrups, suspensions, and emulsions. Medicinal tablets were originally made in the shape of a disk of whatever color their components determined, but are now made in many shapes and colors to help distinguish medicines Tablets are often stamped with symbols, letters, and numbers, which enable them to be identified. Sizes of tablets to be swallowed range from a few millimeters to about a centimeter. Some tablets are in the shape of capsules, and called Caplets. Medicinal tablets and capsules called pills. This is technically incorrect, since tablets are made by compression, whereas pills are ancient sold dose forms prepared by rolling a soft mass into a round shape. Other products are manufactured in the form of tablets which are designed to dissolve or disintegrate; e.g. cleaning and deodorizing products.

- Andrographis paniculata plant has been used for several purposes like Hypoglycemic activity, Cardiovascular activity, Immunological benefits, Hepatoprotective activity, Respiratory system benefits. It is already available in market in powder form. A typical dosage of andographis is 400mg, 3 times a day. Some studies have noted doses as high as 1000 to 2000mg 3 times daily. Tinosporia cordifolia (Giloy) act as a hypoglycaemic agent and since it reduce blood pressure, it is believed to help in curing type 2 diabetes. It is reported to have antioxidant, anti malarial, anti allergic and immunomodulator activity. The study was designed as evaluation of poly herbal formulation as combined tablet of Andrographis paniculata & Tinosporia cordifolia powder for the management of Diabetes mellitus and lowering blood pressure.

OBJECTIVES

- The underlying goal of combination drug product development is to make drug intake more convenient and thereby to improve patient adherence.
- Allows for synergistic combination.
- Reduce the concentration of single herb, thereby reducing adverse events.
- Reduce medication errors.
- Less expensive.

Tabletting Formulations

In the tablet-pressing process, it is important that all ingredients be fairy dry, powdered of granular, somewhat uniform in particle size, and freely flowing. Mixed particle sized powders can segregate during manufacturing operations, which can result in tablets with poor or active pharmaceutical ingredients content uniformity. Content uniformity ensures that the same API dose is delivered with each tablets.

Some APIs may be tableted as pure substances, but this is rarely the case; most formulations include excipients. Normally, a pharmacologically inactive ingredient termed a binder is added to help hold the tablet together and give it strength. A wide variety binders may be used, some common ones including lactose, dibasic calcium phosphate, sucrose, maize starch, microcrystalline cellulose and modified cellulose.

Often, an ingredient is also needed to act as a disintegrant to aid tablet dispersion once swallowed, releasing the API for absorption. Some binders, such as starch and cellulose are also excellent disintegrants.

Small amounts of lubricants are usually added, as well. The most common of magnesium stearate; however, other commonly used tablet lubricants include stearic acid, hydrogenated oil, and sodium stearyl fumarate. These help the tablets, once pressed, to be more easily ejected from the die.

ADVANTAGES

1. Unit dosage forms with accurate, stable dose and great precision and least variability.
2. Most stable with respect to physical, chemical and microbiological attributes.
3. Cheapest oral dosage form, easy to handle, use and carry out with attractive and elegant appearance.
4. Cheap, easy to swallow and production does not require and additional processing steps.
5. Provide prolonged stability to medicaments.
6. Administration of minute dose of drug in accurate amount.
7. Unpleasant taste can be masked by sugar coating.
8. Easy to divide into halves and quarters whenever fraction dose is required.
9. Packing and production is cheap and does not require more space for storage.

DISADVANTAGES

1. Drugs which are amorphous and low density character are difficult to compress into tablet.
2. Hygroscopic drugs are not suitable for compressed tablets.
3. Drugs with low or poor water solubility, sloe dissolution, high absorbance in GI tract may be difficult to formulate.
4. Sensitive to oxygen drugs may require special coating.
5. Cost of production may be increase because of coating and encapsulation to remove bitter and unpleasant taste.
6. Some tablet may cause problem in bioavailability.
7. Difficult to formulate liquid in tablet and swallowing is difficult especially for children and ill patients.

TABLET PROPERTIES

Tablet can be made in virtually any shape, although requirements of patients and tableting machines mean that most are round, oval or capsule shaped.

More unusual shapes have been manufactured but patients find these harder to swallow, and they are more vulnerable to chipping or manufacturing problems.

Tablet diameter and shape are determined by the machine tooling used to produce them - a die plus an upper and a lower punch are required. This is called a station of tooling. The thickness is determined by the amount of tablet material and the position of the punches in relation to each other during compression. Once this is done, we can measure the corresponding pressure applied during compression. The shorter the distance between the punches, thickness, the greater the pressure applied during compression, and sometimes the harder the tablet. Tablets need to be hard enough that they don't break up in the bottle, yet friable enough that they disintegrate in the gastric tract.

Tablets need to be strong enough to resist the stresses of packaging, shipping and handing by the pharmacist and patient. The mechanical strength of tablets is assessed using a combination of (i) simple failure and erosion tests, and (ii) more sophisticated engineering tests. The simpler tests are often used for quality control purposes, whereas the more complex tests are used during the design of the formulations and manufacturing process in the research and development phase. Standards for tablet properties are published in the various international pharmacopeias.

MANUFACTURING

Manufacture of the tableting blend

In the tablet pressing process, the main guideline is to ensure that the appropriate amount of active ingredient is in each tablet Hence, all the ingredients should be well-mixed. If a sufficiently homogenous mix of the components cannot be obtained with simple blending processes, the ingredients must be granulated prior to compression to assure an even distribution of the active compound in the final tablet. Two basic techniques are used to granulate powders for compression into a tablet: wet granulation and dry granulation. Powders that can be mixed well do not require granulation and can be compressed into tablets through direct compression.

Direct compression
The term ‘’direct compression” is defined as the process by which tablets are compressed directly from powder mixture of active ingredients and suitable excipients. No pre treatment of the powder blend by wet or dry granulation procedure is required.

PROCEDURE
- Milling of drug and excipients
- Mixing of drug and excipients
- Tablet compression

Wet granulation
Wet granulation is a process of using a liquid binder lo lightly agglomerate the Powder mixture. The amount of liquid has to be properly controlled, as over- wetting will cause the granules to be too hard and under-wetting will cause them to be loo soft and friable. Aqueous solutions have the advantages of being safer to deal with than solvent-based systems.

PROCEDURE
- The active ingredient and excipients are weighed and mixed.
- The wet granulate is prepared by adding the liquid binder-adhesive to the powder blend and mixing thoroughly.

Example of binders/adhesives include aqueous preparations of cornstarch, natural gums such as acacia, cellulose derivatives such as methyl cellulose, gelatin, and povidone.
- Screening the damp mass through a mesh to form granules.
- Drying the granulations. A conventional tray-dryer of fluid-bed dryer are most commonly used.
- After the granules are dried, they are passed through a screen of smaller size than the one used for the wet mass to create granules of uniform size.

Low shear wet granulation processes use very simple mixing equipment, and can take a considerable time to achieve a uniformly mixed state. High shear wet granualtion processes use equipment that mixes the powder and liquid at a very fast rate, and thus speed up the manufacturing process. Fluid bed granualtion is a multiple-step wet granulation process performed in the same vessel to pre-heat granulate, and dry the powders. It is used because it allows close control of the granulation process.

Dry granulation
Dry granulation processes create granules by light compaction of the powder blend under low pressure. The compacts so-formed are broken up gently to produce granules (agglomerates). This process is often used when the product to be granulated is sensitive to moisture and heat. Dry granulation can be conducted on a tablet press using slugging tooling or on a roll press called a roller compactor. Dry granulation equipment offers a wide range of pressures to attain proper densification and granule formation. Dry granulation is simpler than wet granulation, therefore the cost is reduced. However dry granulation often produces a higher percentage of fine granules, which can compromise the quality or create yield problems for the tablet. Dry granulation requires drugs or excipients with cohesive properties and a dry binder may need to be added to the formulation to facilitate the formation of granules.

Granule lubrication
After granulation, a final lubrication step is used to ensure that the tableting blend does not stick to the equipment during the tableting process. This usually involves low show shear blending of the granules with a powdered lubricant, such as magnesuim stearate or stearic acid.

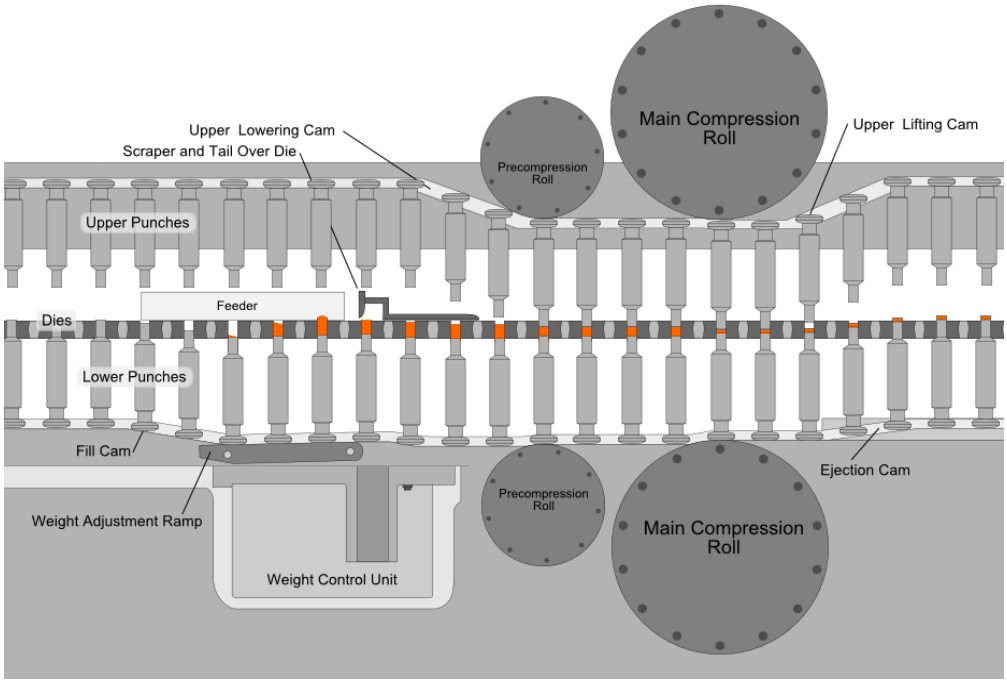
Manufacture of the tablets
Whatever process is used to make the tableting blend, the process of making a tablet by powder compaction is very similar. First, the powder is filled into the die from above. The mass of powder is determined by the position of the lower punch in the die, the cross-sectional area of the die, and the powder density. At this stage, adjustment to the tablet weight are normally made by repositioning the lower punch. After die filing, the upper punch is lowered into the die and the powder is uni axially compressed to a porosity of between 5 and 20%. The compression can take place in one or two stages (main compression, and, sometimes, pre-compression or tamping) and for commercial production occurs very fast (500-50 m sec per tablet). Finally, the upper punch is pulled up and out of the die (decompression) and the tablet is ejected from the din by lifting the lower punch until its upper surface is flush with the top face of the die. This process is simply repeated many times to manufacture multiple tablets.

Common problems encountered during tablet manufacturing operations include
- Poor (low) weight uniformity, usually caused by uneven powder flow into the die.
- Poor (low) content uniformity, caused by uneven distribution of the API in the tableting blend.
- Sticking of the powder blend to the tablet tooling, due to inadequate lubrication, dirty tooling and sub-optimal material properties.
- Capping, lamination or chipping. Such mechanical failure is due to improper formulation design or faulty equipment operation.

Tablet compaction simulator
Tablet formulations are designed and tested using a laboratory machine called a Tablet compaction simulator or powder compaction simulator. This is a computer controlled device that can measure the punch positions, punch pressures, friction forces, die wall pressures, and sometimes the tablet internal temperature during the compaction event. Numerous experiments with small

quantities of different mixtures can be performed to optimize a formulation. Mathematically corrected punch motions can be programmed to simulate any type and model of production tablet press. Initial quantities of active pharmaceutical ingredients are very expensive to produce, and using a compaction simulator reduces the amount of powder required for product development.

Tablet presses



The tablet pressing operation: Tablet presses, also called tableting machines range from small, inexpensive bench-top models that make one tablet at a time (single-station presses), with only around a half-ton pressure, to large, computerized, industrial models (multi- station rotary presses) that can make hundreds of thousands to millions of tablets an hour with much greater pressure. The tablet press is an essential piece of machinery for any pharmaceutical and nutraceutical manufacturer.

Common manufacturers of tablet presses include Fette, Korsch, Kikusui, Manesty and Courtoy. Tablet presses must allow the operator to adjust the position of the lower and upper punches accurately, so that the table weight, thickness and density can each be controlled. This is achieved using a series of cams, rollers, and/or tracks that act on the tablet tooling (punches).

Mechanical systems are also incorporated for die filing, and for ejecting and removing the tablets from the press after compression. Pharmaceutical tablet presses are required to be easy to clean and quick to reconfigure with different tooling, because they are usually used to manufacture many different products.

REVIEW OF ANDROGRAPHIC PANICULATA

Common name: Kalmegh, Kiryat, Senshinren, Kirata
Botanical name: Andrographis paniculata
Family: Acanthaceae
Part used: Leaves and tender shoots

Introduction: It is a principal herb in the domestic medicine called 'Alui', which is given to infants. Both in Ayurveda and Unani, it is confused with 'Chitetta', but both are different plants. It is widely available in Arabia. It is given for fever along with several herbs. It was advertised in England as a substitute for quinine. For centuries, the Ayurvedic practitioners of India have used the roots and leaves of the herb Andrographic Paniculata to treat ailments ranging from poor digestion to hepatitis. In the Chinese medical tradition, the plant has been used to treat everything from gastrointestinal complaints to throat infections. Although some early scientific studies suggested that andrographis has a antimicrobial action, the weight of clinical evidence now shows that the real value of the ancient herb is as a stimulant for the immune system.

Origin: It grows throughout the India from Assam and Himachal Pradesh to all over South India. Grows well in moist and shaded places, but it prefers sunny situations. It is cultivated all over India.

Chemical Composition: Bitter diterpenoids lactones, especially dioxy- andrographolide, andrographolide and ncoandrographolide have been isolated from the whole plant and leaves. Diterpene dimers. Flavonoids avaialable in the roots. The main active constituents and marker compounds are considered to be the andrographolide and andrographis extracts are often standardized to these compounds.

Pharmacology: It increases biliary flow and liver weight in rat. Andrographolide produces a significant dose dependent choleretic effect, as evidence by increase in bile flow, bile salt and bile acids in conscious rats and anaesthetized guinea pigs. It shows hepato protective action. It improves non-specific immune response. Although both andrographis and beta glucan are effective immune enhancers, Extracts of andrographis, have been shown to stimulate powerful immune responses in living creatures. The immune response may be specific directed at a microbial invader already present in the body, or generally, strengthening the immune system in preparation against future infection. Andrographis strongly stimulates phagocytosis and the production of specific antibodies.

Therapeutic uses
Digestive: Promotes digestion
Hepatoprotective: Protects the liver and gall bladder
Vermicide: Kills intestinal worms & support intestine
Anti acne: Protect skin from pimples.
Analgesic: Pain killer.
Anti-inflammatory: Reduces swelling due to exudation from capillaries
Antibacterial: Fights bacterial activity. Although Andrographis appears to have weak direct antibacterial action, it has remarkably beneficial effect in reducing diarrhea and symptoms arising from bacterial Infections.
Expectorant: Promotes mucus discharge from the respiratory system.
Hypoglycemic: Blood sugar reducer. Immune Enhancement.
Laxative: Aids bowel elimination
Sedative: A relaxing herb, though not with the same effect as the accepted herbal sedatives, valorian routs, hops, skullcap, etc.
Dosage: A typical dosage of andrographis is 400 mg, 3 times a day. Some studies have noted doses as high as 1,000 to 2,000 mg 3 times daily.

Andrographis is usually standardized to its content of the active constituent, andrographolide, which is typically 4-6%. Products should be stored in airtight containers and protected from light and moisture.

Review of Tinospora cordifolia
Common Name: Gulanshe Tinospora, Gulancha Tinospara, Tinospara, Giloy
Botanical Name: Tinospora cordifolia
Family Name: Menispermaceae
Part Used: Stem and roots

Introduction: Tinospora cordifolia, also called Guduchi is an herbaceous vine of the Family: Meningermaceae indigenous to the tropical areas of India, Myanmar and Sri Lanka. The plant is a glabrous climbing shrub found throughout India, typically growing in deciduous and dry forests. The leaves are heart shaped. The succulent bark is creamy white to grey in color, with deep clefts spotted

with lenticles. Flowers are yellow, growing in lax racemes from nodes on old wood. Fruits are drupes, turning red when ripe.

Origin: It is cultivated throughout the India but mostly cultivated in North and South India.

Pharmacology: The water and ethanolic extract of stem inhibited the cyclophophamide induced immuno supression. Aqueous of the stem showed anti-inflammatory, analgesic and anti pyretic properties in rats. In clinical studies, it showed immunosuppressive properties in jaundice patients, antioxidant activity and amelioration of Cyclophosphamide induced toxicity.

Constituents: Tinosporic acid, cordifoliside A to E, syringen, the yellow alkaloid, berberine, Giloin, crude Giloininand, a glucosidal bitter principle as well as polysaccharides, including arabinogalactan polysaccharide (TSP). Picrotene and bergenin, were also found in the plant

Uses: It is an Anti periodic, Antipyretic, Alternative, Diuretic, Anti inflammatory. It is a constituent of several compound preparation. It is used in fever, urinary disorders, dyspepsia, general debility and urinary diseases. It is also used in treatment of rheumatism and jaundice.

Dosage: Powder: 3 to 6 g

MATERIALS AND METHODS

Chemicals & Instruments

Powders of Andrographis paniculata & Tinosporia cordifolia were purchased from local market. Starch is used as a binder. Acacia is also used as a binder. Magnesium stearate is used as a lubricant. Other instruments used are hot air oven, mesh screen, sieve no 20 & 40, compression machine, friabilator, monsato tester, pfizer tester, strong cobb tester, micrometer calipers.

METHODS

Method for the preparation of granules and tablets.

Ingredients	Weight for one tablet	Weight for 300 tablets
Tinosporia cordifolia	300 mg	90 mg
Andrographic paniculata	150 mg	45 mg
Starch	45 mg	13.5 mg
Acacia	10 mg	3 mg
Magnesium stearate	5 mg	1.5 mg
Average	510 mg	153 mg

Wet granulation method for the preparation of granules

1) Weigh the powder of Tinosporia cordifolla, Andrographic paniculata and starch according 300 tablets.
2) Pass the powder individual from the sieve no. 40 & mix all three powder. And also pass the magnesium stearate from sieve no. 40 & keep it separate.
3) Granulate, step-2 by using acacia as a binder taking in 30 ml water.
4) Pass it through sieve no. 10.
5) Dry it in hot air oven for appropriate time at 60°c for 30 minutes.
6) Again pass it through sieve no. 20 & mix the un lubricated blend with magnesium stearate for 5 min.
7) Then, use these lubricated granules for preparation of tablets by using compression machine.

Evaluation test for tablet

Weight variation test
Disintegration test
Friability test
Hardness test
Size & shape

Weight Variation Test

Purpose: To check the uniformity of weight of tablet.
Method: Take 20 tablets

- Weigh individual tablet
- Find out the mean weight of tablet
- Find out wt. deviation of tablet
- Find out %wt. deviation

Interpretation: Tablet pass the test, if not more than 2 tablet deviate from the standard rang.

Disintegration test

Purpose: To know the disintegration time of tablet.
Instrument: Consist basket of 6 glass tube open at top and at bottom there is 10 mesh screen.
- Distance of moving of basket is 5-10cm at frequency of 28 to 32 cycles per min.
- Temperature of fluid-37±2° C.

Standard range table

Pharmacopeia	Weight range	Standard range
U. S. P.	Up to 130 mg	10%
	130-324 mg	7.5%
	324 or more	5%
B.P. & I. P.	Up to 80 mg	10%
	80-250 mg	7.5%
	250 or more	5%

Method

- Place 1 tablet in a each tube and basket rack is positioned in a 1Lt of beaker contain water / stimulated gastric fluid /simulated intestinal fluid 37±2° C such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement.
- Move the basket assembly at rate of 28 - 32 cycles per min.
- Measure the time when all the tablet disintegrate and pass through 10 mesh screen.

- According to the test the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified.

Standard
Uncoated tablet: 15 min.
Coated tablet: 1-2 hrs.

Hardness test
Purpose: It measure the tablet crushing strength, all the tablet should have the sufficient strength to withstand mechanical shake during handing, transportation, packaging.

Method: Tablet is held in between fixed and moving jaws and pressure is applied by turning screw, note down pressure when tablet is crushed.

Limit: Usually 4 kg is satisfactory for tablet.

Apparatus
1) Monsanto tester

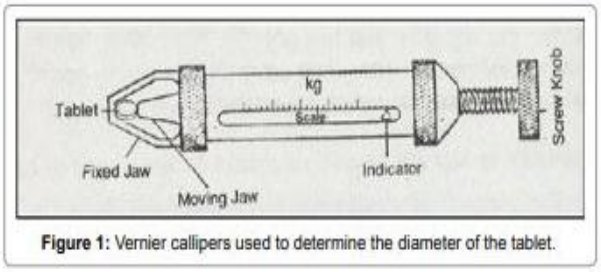


Figure 1: Vernier callipers used to determine the diameter of the tablet.

2) Pfizer tester

3) Strong cobb tester

Friability test
Purpose: To check the crushing strength of surface of tablet.
Apparatus: Roche friabilator -Consist of circular plastic chamber
Speed of rotation: 25 rpm
Dropping distance: 15 cm

Method
- Take 10 tablet weigh it.
- Then put into friabilator.
- Start apparatus and after 100 rpm stop it.
- Again weigh tablet
- Find out the % friability.

Limit Less than 1%.

Diameter and thickness: Diameter & thickness is measured with the help of micrometer calipers.

RESULTS AND DISCUSSION

Pre formulation study of powder & granules

Bulk density
For powder, V_b = Mass/ Bulk Volume
= 20/44
= 0.454gm/ml

For granules, V_b = Mass/ Bulk Volume
= 20/49
= 0.403gm/ml

Tapped density
For powder, V_t = Mass/Tapped Volume
= 20/ 24.8 = 0.806gm/ml
For granules, V_t = Mass/Tapped Volume
= 20/ 40 = 0.5gm/ml

Carrs index
For powder, I =
$V_t - Vb/Vt \times 100$
$= 0.806 - 0.454/ 0.806 \times 100$
= 43.67%

For granules, $I = Vt - V_b/ Vt \times 100$
$= 0.5 - 0.403/ 0.5 \times 100$
= 19.4%

Hausners ratio
For powder, $H = V_t/Vb$
= 0.806/0.454
= 1.775

For granules, $H = Vt/V_b$
= 0.5/ 0.403
= 1.24

Angle of repose
For powder, $\Theta = \tan^{-1}$ (h/r)
$= \tan^{-1}$ (2.5/3.2)
$= \tan^{-1}$ (0.78)
= 37.99°

For granules, **Θ** = $\tan^{-1}$ (h/r)
=0 $\tan^{-1}$ (2.5/4.4)
= $\tan^{-1}$ (0.56)
= 29.24°

Parameter	For Powder	For Granules
Bulk density	0.454gm/ml	0.403gm/ml
Tapped density	0.806gm/ml	0.5gm/ml
Carrs index	43.67%	19.38%
Hausners ratio	1.775	1.24
Angle of Repose	37.99°	29.24°

Disintegration time

Sr. No	Disintegration Time (min)
1	2.8
2	3.0
3	3.0
4	2.8
5	3.0
	AVERAGE = 2.92

Weight variation test

Sr. No.	Weight of Tablets (mg)	Deviation	% Deviation
1	490	0.009	-1.803
2	490	0.009	-1.803
3	500	0.001	0.200
4	510	-0.011	2.204
5	520	-.0021	4.208
6	490	0.009	-1.803
7	490	0.009	-1.803
8	500	0.001	0.200
9	510	-0.011	2.204
10	520	-.0021	4.208
11	490	0.009	-1.803
12	500	0.001	0.200
13	490	0.009	-1.803
14	490	0.009	-1.803
15	500	0.001	0.200
16	500	0.001	0.200
17	510	-0.011	2.204
18	490	0.009	-1.803
19	590	0.009	-1.803
20	500	0.001	0.200

AVERAGE = 0.499

Hardness

SR. NO.	HARDNESS (kg/cm^2)
1	4.0
2	4.0
3	5.0
4	4.0
5	4.5
	AVERAGE = 4.3

Thickness

SR. NO.	THICKNESS (mm)
1	4.0
2	4.0
3	3.5
4	4.0
5	3.5
	AVERAGE = 3.8

Friability
Initial weight of 10 tablets:- 4.85gm
Final weight of 10 tablets (after friabilation):- 4.83gm
%Friability = initial wt of tablets − final wt of tablets / initial wt of tablets X 100
= 4.85 − 4.83/4.85 X 100
= 0.41%

DISCUSSION

- According to Indian Pharmacopeia, the tablet passed the weight variation test because the maximum variation is 4.209 and minimum variation is -1.803 so, the tablet passed the weight variation test.
- Disintegration test (less than 15 minute) is passed as per the IP.
- Friability test (less than 1%) is passed as per the IP.
- Hardness test is passed as per the IP.

CONCLUSION

From the observation and result it can be concluded that the granules has good flow property than powder according to the Carrs index and Hausners ratio and from the results the tablets were pass all the parameter.

It proves the authenticity of powder of herbal plants but the combination of both the herbal plants will need further development of TLC system & also the need of development of dissolution method and estimation of these poly herbal formulation.

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