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Research Article

**FORMULATION AND EVALUATION OF HERBAL TABLETS
FOR DIABETES AND HYPERTENSION****Mrs. Bhavana Patil*, Shivani Darade, Divya Bagul, Ayush Bhankar,
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Abstract:

Increased circulatory fluid volume and peripheral vascular resistance are closely associated to elevated blood pressure. Patients with diabetes mellitus experience increased peripheral arterial resistance brought on by vascular remodeling, as well as an increase in body fluid content brought on by hyperinsulinemia and hyperglycemia brought on by insulin resistance. These two processes both raise blood pressure throughout the body. Since type 2 diabetes has a natural history, understanding the pathophysiology of hypertension in diabetes mellitus needs familiarity with this condition. Due to poor glucose tolerance and early-stage diabetes, patients have hyperinsulinemia and insulin resistance. Increased bodily fluid content is the cause of hypertension. Diabetes has advanced to the mid-stages at this point, and peripheral vascular resistance and vascular remodeling both play a role in hypertension. Additionally, vascular remodeling has a big impact on diabetes complications. Particularly, higher glomerular pressure is brought on by afferent arteriolar remodeling during diabetic nephropathy. Our present work deals with the development and evaluation of herbal tablet which is used for the treatment of diabetes and hypertension containing paneer phool shatavari, Arjunsal, S.musli ,Chirayata , Kutaki, Shilajit Stevia etc . All the above mention plant ingredients were reported for having good antidiabetic antihypertensive and antioxidant activity.

KEY WORDS: Paneer phool shatavari, Arjunsal, S.musli ,Chirayata , Kutaki, Shilajit Stevia, Vijaysar.

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INTRODUCTION:

Solid medicaments may be administered orally as powders, pills, cachets, capsules or tablets. These dosage forms contain a quantity of drug which is given as a single Unit and they are known collectively as solid unit dosage forms, even in the case of Sustained action preparations which, technically, contain the equivalent of several Normal doses of drug. The stringent formulation requirements of modern Medicaments, the many advantages of tablet and capsule medication, coupled With expanding health services and the commitment need for large-scale Economic manufacture, have led to a steady decline in the prescribing of powders And pills. Tablets and capsules, on the other hand, currently account for well over Two third of the total number and cost of medicines produced all over the world. Tablets are solid dosage form which is the conventional as well as have many advantages over other dosage forms.

Tablets are the most popular dosage form; about 70% of the total medicines are dispensed in the form of tablet.⁷ Tablets had different shapes, sizes, as well as weight depending on medicinal substances and the intended mode of administration. In this paper the some advantages as well as some disadvantages of tablets, the basic ingredients that are commonly found in tablets, methods of tablet preparation and the various types of the tablets are briefly reviewed. Definition According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drugs or a mixture of drugs, with or without diluents. Tablet is defined as a compressed solid dosage form Containing medicaments with or without excipients. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration.

PROPERTIES

- 1) Should be elegant product having its own identity while being free of defects such as chips, cracks, discoloration and contamination.
- 2) Should have strength to withstand the rigors of shocks encountered in its production, packaging, shipping and dispensing.
- 3) Should have the physical stability to maintain its physical attributes over time.
- 4) Must be able to release the medicament agent(s) in the body in a predictable and reproducible manner.
- 5) Must have a suitable chemical stability over time so as not to allow

alteration of the medicinal agent(s).

ADVANTAGES

- 1) Tablets are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
- 2) They are easiest and cheapest to package and strip.
- 3) Low in cost.
- 4) Lighter and compact.
- 5) Having greatest chemical and microbial stability over all oral dosage forms
- 6) Suitable for large scale production.
- 7) Easy to swallow with least tendency for hang-up.
- 8) Objectionable odour and bitter taste can be masked by coating technique.
- 9) Sustained release product is possible by enteric coating.
- 10) Easy to handling.

DISADVANTAGES

- 1) Difficult to swallow in case of children and unconscious patients.
- 2) Some drugs resist compression into dense compacts, owing to amorphous nature, low-density character.
- 3) Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.
- 4) Bitter tasting drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.
- 5) Irritant effects on the GI mucosa by some solids (e.g., aspirin).
- 6) Possibility of bioavailability problems resulting from slow disintegration and dissolution

INGREDIENT

- 1) Diluents: Diluents are fillers used to make required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk. Also used to improve cohesion, to permit use of direct compression.⁹
- 2) Binders: to form cohesive compacts for directly compressed tablet.
- 3) Lubricants: Lubricants are intended to prevent adhesion of the tablet materials to the surface of dies and punches, reduce inter particle friction and may improve the rate of flow of the tablet granulation.

- 4) Glidants: Glidants are intended to promote flow of granules or powder material by reducing the friction between the particles.
- 5) Anti-adherents: Anti-adherents are added to the tablet formulations to prevent the material from sticking to the walls of the tablet press.
- 6) Wetting Agents: They help in the wetting of the tablet in contact with water in the GIT.
- 7) Colouring Agents: The use of colors and dyes in a tablet has three purposes:
 - (A) Masking of off color drugs
 - (B) Product Identification
 - (C) Production of more elegant product.
- 8) Flavouring Agents: Flavouring oils are needed for chewable tablets. The oil is generally added in a dry form such as spray-dried beads.
- 9) Absorbents: The inclusion of absorbents in a tablet formulation is necessary if the product contains substances with a high affinity to water. Hygroscopic materials, if present, render the blend wet and difficult to handle during manufacture.

LITERATURE REVIEW

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MATERIALS AND METHODS:

SR NO.	INGREDIENTS	ROLES
1	Paneer phool	It has ability to regulate the level of insulin inside our cells also helps repair the beta cells of the pancreas which produce insulin in body.
2	Shatavari	
3	Arjunsal	It has Antihypertensive property and helps reduce high blood pressure also Beneficial in reducing blood sugar level.
4	S.musuli	It shows blood glucose lowering activity.
5	Chirayata	It has Antioxidant & Anti-inflammatory properties. It enhances the release of Insulin.
6	Shilajit	It improves lipid profile.
7	Stevia	It act as a vasodialator and lowering the blood pressure.It is use as a substitute for sugar and other sweetner.
8	Kutki	It act as antidiabetic and hypocholesterolaemic that makes it a rejuvenating herb for diabetes.
9	Vijaysar	It improves blood circulation and prevent pancreatic cells against the damage caused by free radicals and enhances insulin secretion.

ROLE OF INGREDIENTS:-**1.KUTKI**

Biological name- It consist of dried rhizome of picrorhiza kurroa royle ex benth, cut intosmall pieces and freed from attached root. It belongs to family Scrophulariaceae.

Geographical source

It is found in the Himalayan regions of China, Pakistan, India, Bhutan and Nepal.

Chemical constituents

It consist of chemical constituents such as picroside I,II ,d-mannitol ,kutkitol

,kutki sterol andapocynin.

Benefits / Uses

- It can be used as an appetizer.
- Decoction of kutki with honey or kutki powder with sugar is used to treat jaundice inayurveda .
- Kutki is also to make an ayurvedic formulation name arogyavardinvati to treat liver diseases.
- In ayurveda kutki is used with various herbs to manage viral hepatitis and fatty liver.

2. VIJAYSAR**Biological source**

Vijaysar is a plant drug used in Ayurvedic medicine .It is scientifically known as Pterocarpusmarsupium and belongs to the

Fabaceae family.

Geographical source

This trees are found in large quantity in south indian states like karnataka, kerala.

Chemical constituents

It consist of chemical constituents such as fats,flavanoids, glycosides, alkaloids, saponins and tannins.

BENEFITS/USES

➤ It is extensively used or the treatment of diabetes ,obesity ,diarrhea ,vitiligo ,eczema ,psoriasis etc in ayurveda.

3.Arjunsal



Biological Source:

Arjun consists of dried stem bark of the plant known as terminalia Arjuna Rob, belonging to family Competencies. It contain not less than 0.02 percentage of arjun genin on dried basis.

Geographical Source:

In the Indian Peninsula, the tree is widespread. It is widely planted in the Chotta Nagpurregion along streamside's.

Chemical Constituent:

Arjuna contain following chemicals a mixed form of tannin that includes both hydrolysable and condensed tannins. According to reports, the tannins include ellgic acid, (+) catechol, (+)gallo catechol, epicatechol, and epigallo catecho, flavonoids such arjunolone, arjunone, and baicalein have been identified.

Uses:

- Arjuna bark is employed as an astringent and diuretic.
- Triterpenoids found in fruits are responsible for the diuretic effects. Both blood pressure and heart rate decrease as a result.
- In indigenous medical systems, it is utilised to treat

a variety of heart ailments.

4.Ratanjot



Biological Source:

Ratanjyot consist of dried roots of plant known as Alkanna Tinctoria belonging to family Boraginaceae .

Geographical Source :

Its mainly found in North Africa , South Europe,Greece ,Turkey , Syria .

Chemical Constituent :

The major compounds detected in the oil, were pulegone (22.27%), 1,8-cineole (13.03%), α -terpinyl acetate (6.87%), and isophytol (6.83%)

5.S.MUSLI:-



BIOLOGICAL SOURCE:-

S.Musli is a herb with lanceolate leaves, from tropical wet forests in peninsular India.

GEOGRAPHICAL OCCURRENCE:-

S. musli is a herb commonly found in some patches of forest areas of whole of India as wellas in Maharashtra State.

CHEMICAL CONSTITUENTS:-

S.Musli roots contain glucose, protein, fibre, and saponin, alkaloids, saponins, polysaccharide, and protein.

BENEFITS/USES:- 3□

S.Musli is used in traditional systems of medicine including Ayurveda, Unani, and homeopathy.

□ People use safed musli for athletic performance, obesity, erectile dysfunction (ED), and other conditions.

□ Safed musli has a strong hypoglycaemic effect, which is essential for controlling blood sugar levels in the body.

It also contains antioxidants, which may benefit the pancreas against damage. This may aid in the improvement of insulin levels.

6.CHIRAYATA:-**BIOLOGICAL SOURCE:-**

The herbal drug “chiretta” obtained from the dried plants of swertia species. The whole plants of Swertia are medicinal but roots are the most powerful parts.

GEOGRAPHIC OCCURRENCE:-

It is mainly found in India, Nepal and Bhutan.

CHEMICAL CONSTITUENTS:-

Chirata contains several compounds that contribute to its medicinal value.

The compounds include Xanthenes, alkaloids, and

glycosides. They also consist of ophelic acid, chiratin, steric acid, oleic acid, and palmitic acid. Swertanone, amarogenin, and chiratol are other important components present in Chiraita.

BENEFITS/USES:- Chirata may be helpful in various problems related to the digestive system like gastritis, indigestion (upset stomach), gas accumulation in the stomach, bloating, heartburn and stomach pain.

It also contains laxative properties and is helpful in constipation.

It is also effective in treating diarrhea.

7.Paneer phool:-**Biological source:-**

Paneer phool is dried pods of withania coagulans belonging to family Solanaceae or nightshade.

Geographic occurrence:-

Paneer phools are mostly found in Afghanistan, Pakistan and Indian subcontinents.

Chemical Constituents:-

Paneer phool contains carbohydrates, free sugar, amino acids, essential oil, fatty oil, alkaloids, steroids, tannins, phenolic compounds, and esterase.

Benefits/Uses:-

➤ Paneer ka phool is a herb that is used to manage diabetes.

➤ It has abilities to regulate the level of insulin inside our cells.

➤ It also helps repair the beta cells of the pancreas which produce insulin in our body.

➤ Beta cells get damaged when the person is diabetic and are thus unable to produce insulin.

8. Shatavari:-**Biological Source:**

Shatavari is dried root of plant *Asparagus racemosus* belongs to family Liliaceae and commonly known as Satawar, Satamuli.

Geographic occurrence:-

The Shatavari is popularly grown in Indian states like Arunachal Pradesh, Delhi, Assam, Chhattisgarh, Gujarat, Kerala, Punjab, Himachal Pradesh, Haryana, and Jharkhand.

Chemical Constituents:-

The active constituents are steroidal saponins, such as, Shata-varin I-IV (0.1–0.2%). The aglycone unit is sarsapogenin. In shatavarin I three glucose and one rhamnose molecules are attached whereas shatavarin IV possesses two glucose and one rhamnose molecules. The other compounds isolated from *A. racemosus* are β -sitosterol, stigmasterol, their glycosides, sarsapogenin, spirostanolic acid, furostanolic saponins, 4,6-dihydroxy-2-O-(2'-hydroxy-isobutyl) benzaldehyde, undecanyl cetanoate and polycyclic alkaloid asparagine A

Benefits/Uses:

- It reduces blood pressure and improves blood circulation
- It reduces intestinal absorption of glucose
- It helps to lower the blood glucose level.

9. Shilajit**Biological source:**

Shilajit is a natural substance found mainly in the Himalayas, formed for centuries by the gradual decomposition of certain plants by the action of microorganisms.

Geographic occurrence:

Shilajit is a natural substance found mainly in the Himalayas, formed for centuries by the gradual decomposition of certain plants by the action of microorganisms.

Chemical Constituents:

The constituents present in Shilajit are mainly fulvic acid, dibenzo- α -pyrones, humic acids, humins together with fatty acids, triterpenes, aromatic carboxylic acids, phytophenols and many other phytochemicals. The primary component of Shilajit is fulvic acid which contribute to cognitive health.

Benefits/Uses:

- Enhances Fertility and Testosterone Levels.
- Improves Brain Functioning.
- For Treating Anaemia.
- Altitude Sickness.
- Keeps You Younger.
- Improves Heart Health.
- Reducing Stress and Anxiety Levels.

10. Stevia:-**Biological source:**

Stevia rebaudiana, a Paraguayan herb that produces an intensely sweet diterpene glycoside called stevioside, is the most relevant member of this genus. Apart from *S. rebaudiana*, many other species belonging to the *Stevia* genus are considered medicinal and have been popularly used to treat different ailments.

Geographic occurrence:

The genus Stevia is distributed all over the world, ranging from the southern parts of USA to Argentina and the Brazilian highlands, across Mexico, the Central American States, and the South American Andes.

Benefits/Uses:

➤ Stevia is often touted as a safe and healthy sugar substitute that can sweeten up foods without the negative health effects linked to refined sugar.

➤ It's also associated with several impressive health benefits, such as reduced calorie intake, blood sugar levels, and risk of cavities

Extraction Process:-**Extraction of Paneer Fool:-**

- Soak pieces of paneer fool in water overnight.
- Next morning squeeze out the paneer fool to bring out the extract in water.
- Filter it through filter paper.21

Formulation of tablets:-

INGREDIENTS	F1H	F2H	F3H
PANEER PHOOL	10	10	10
S.MUSLI	5	5	5
CHIRAYATA	5	5	10
ARJUNSAL	5	5	10
SHILAJIT	5	5	5
STEVIA	10	10	5
KUTAKI	5	5	5
SHATAVARI	5	5	5

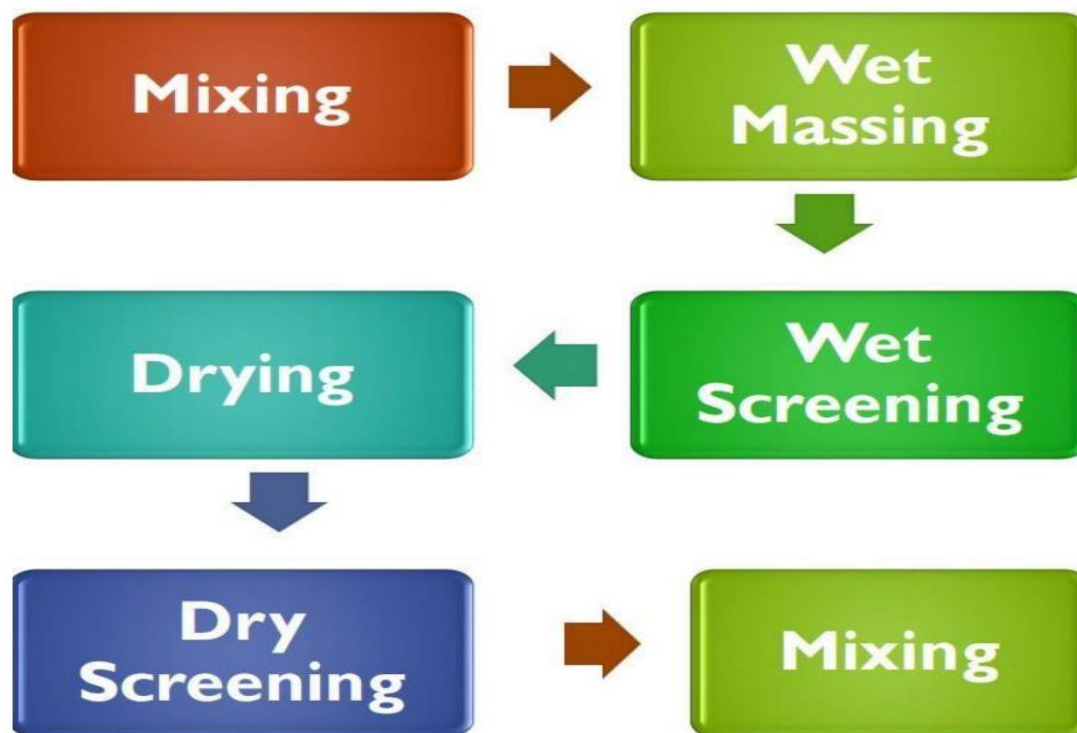
Preparation of tablet:-

- 20 g of paneer Phool soaked in 50ml of water overnight .
- Wt 10 g of each herbs powder like Paneer fool, Kutki, Shatavari, Chirayata etc.
- All herbal powder are pass through sieve no 80
- Add paneer fool extract in mixture of herbal powder to form wet mass.
- Dried in oven for 30 min at 120 degree Celsius .
- Mixed all the mixtures properly .
- Punch the mixture using rotary tablet punching machine.

Wet Granulation:-

The wet granulation technique uses the same preparatory and finishing steps of direct compression and dry granulation (dry screening and mixing); it also involve additional stepsof wet massing, wet screening and drying.

Steps of Wet Granulation:-

**1- Mixing**

• Mixing starts with adding drug then excipients. The mixing process depends on the properties of the drug and excipients.

◦ If the drug is soluble in water and excipients are little; so we start to add binder solution to the drug to be distributed uniformly then excipients that have little solubility in water (e.g. starch), it is possible to be added extragranularly [as a whole] or [divided and added as one half intragranular and the other extragranularly to avoid getting friable tablets]. Total amount of disintegrant is not always added completely to the powder-diluent mixture (intragranular), some other portion might be added with lubricants (extragranular) in the final step prior to

2- Wet Massing

Adhesive (binder) is most commonly employed as solution, suspension, slurry, or used as a dry powder. Method of introducing the binder depends on its solubility and on the components of the mixture (wettability). In the wet massing step the binder solution will distribute and fill the spaces between particles. The primary force of granulation act as a bridge and is obtained from surface tension. Once the liquid is added, mixing is continued

until we get a uniform dispersion of the adhesive within the whole system. The length of wetting time depends on the wetting property of the powder mix. and the granulating fluid, and on the efficiency of the mixer. The end point can be determined by the press mass test (ball test) as

the mass must be moisten rather than pasty or wet, it is done by pressing a portion of the mass in the palm if the ball crumbles under a moderate pressure, the mixture is ready for the next step (wet screening).

3- Wet Screening (granulation)

Granulation is performed to obtain a discrete granules and further consolidate the granules by increasing the particles contact points, and also to increase surface area to facilitate the drying process.

4- Drying

After drying step the granules should contain some degree of humidity to act as a binder (not be 100% free of humidity) as over drying may lead to weak force and friable granules.

The final cohesive force obtained after drying stage when evaporation of solvent occur as a result of fusion, recrystallization and curing of the binding agent with Van der Waals forces playing a significant role

5- Dry screening

After drying; then dry screening is performed to get a homogenized granules with uniform size and shape.

6- Mixing

By addition of lubricants and glidants. Therefore, the granules will possess good compressibility (good cohesive forces once applying punch forming solid impact tab.), good flowability (spherical shape that is the ideal physical form in providing smoothness and size uniformity to the particles which is easily flow).

Advantages of wet granulation method:

1. Improve flowability, cohesiveness and compressibility of the powder, so the powder is easily compressed with lower binder concentration (due to the stick of powder particles together that are surrounded by layer of a binder) in addition to the low pressure and low energy comparing to dry granulation (prolong machine age).
2. Can be used for high dose drug with weak compressibility that is not affected by heat and moisture.
3. Maintaining uniform distribution for low dose drug and water soluble dyes (coloring agent).
4. Improve the dissolution rate of hydrophobic drug because of the presence of moisture of the already used water.
5. Maintaining good content uniformity due to prevention of particle segregation since all the granules will have the same density (same constituent of the powder mixture).

Disadvantages of wet granulation method:

1. cost-time consumer
2. Personal and environmental hazards upon using organic solvents represented by the flammability and toxicity of these solvents after evaporation during drying, handling or storage.
3. Stability problem because of the presence of moisture speeds up the reaction between active ingredients and the additives and the additives itself.

Evaluation Tests of Tablets:

Non-Official Tests

- 1.] General appearance
 - i) Organoleptic property.
 - ii) Size & Shape.
 - iii) Thickness.
- 2.] Hardness.
- 3.] Friability.

Official Test:-

- 1.] Weight variation.
- 2.] Dissolution.
- 3.] Disintegration .

Non-Official Tests:

1] General appearance:-

The general appearance of a tablet its visual identity and overall “elegance” is essential for consumer acceptance, for control of lot-to-lot uniformity Appearance of a tablet involved the measurements of a tablet's :-

- Size
- Shape
- Colour
- Odour
- Taste
- Surface texture.

1] Organoleptic Properties



Many pharmaceutical tablets use colour as a vital means of rapid identification and consumer acceptance The color of product must be uniform within a single tablet

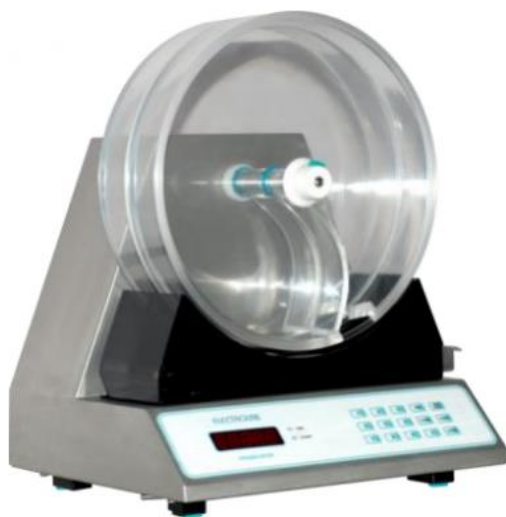
2] Size and Shape Tablet thickness should be controlled within $\pm 5\%$ variation of standard value.²⁶ More likely to cause capping problem

2] Hardness:-

Tablets require a certain amount of strength, or hardness and resistance to friability to withstand mechanical shocks of handling in manufacture packing and shipping Hardness thus sometimes termed the tablet crushing strength.

3] Friability:

The friability test is official in USP but not in BP and IP Friability tester is known as the Roche Friabilator Tablet hardness is not an absolute indicator of strength since some formulation, when compressed into very hard tablets.



Procedure:-

- Pre weight tablet sample placed in friabilator
 - Operated 100 revolution (25rpm for 4 min)
 - Dropping tablet a distance 6 inch
 - Tablet are then dusted and reweighed
- Conventional compressed tablets that lose less than 0.5 to 1% of their weight are generally acceptable

1] Weight Variation:-

The weight variation of tablet being made is routinely measured to help ensure that a tablet contains the proper amount of drug As per Indian pharmacopeia weight 20 tablets selected at random and determine the average weight .Not more than 2 of the individual weights deviate from the average weight by more than the percentage deviation shown in table.

2] Dissolution:-

Dissolution is the process by which a solid solute enters a solution Pharmaceutically it may be defines as the amount of drug substance that goes into solution per unit

time under standardized conditions of liquid/solid interface,temperature and solvent composition

Dissolution kinetics is important in determining the bioavailability of a drug.

- It is carried out in USP dissolution apparatus type I (Basket type)
- In general a single tablet is placed in a small wire mesh basket fastened to the bottom of the shaft connected to a variable speed motor
- The basket is immersed in the dissolution medium contained in a flask. The flask is maintained at constant temperature of $37 \pm 5^\circ\text{C}$ by a constant temperature bath
- The motor is adjusted to turn at the specified speed, and samples of fluid are withdrawn at intervals to determine the amount of drug in solution.



3] Disintegration:-

It is the time required for the tablet to break into particles, the disintegration test is a measure only of the time required under a given set of conditions for a group of tablets to disintegrate into particles.

Liquids used in disintegration were water and Stimulated gastric fluid (1M Conc HCL). The tablet disintegrates in 27 seconds



Conclusion:-

Herbal products may contain a single herb or combinations of several different herbs believed to have complementary and/ or synergistic effects. Some herbal products, including many traditional medicine formulations, also include animal products and minerals.

Herbal products are sold as either raw plants or extracts of portions of the plant. Present study deals with formulation and evaluation of the tablets made from Paneer phool, Shatavari, Arjunsal, S. Musuli, Chirayata, Kutki Vijaysar, Shilajit, Stevia. The anti diabetic and anti hypertensive activity was reported

which was found to be significant. This holds great promise for future research for the formulation of potent antidiabetic and anti hypertensive drug for the present plants.

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