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Original Research Article

Pharmaceutical formulation and quality control for Guggil -100 tablet (*Commiphora mukul)*

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Abstract: Today's World Pharmaceutical formulation, in pharmaceutics, is the process in which different chemical substances are combined to a pure drug substance to produce a final medicinal product. Formulation studies involve developing a preparation of the drug which is both stable and acceptable to the patient. For orally taken drugs, this usually involves incorporating the drug into a tablet or a capsule. It is important to appreciate that a tablet contains a variety of other substances apart from the drug itself, and studies have to be carried out to ensure that the drug is compatible with these other substances. In this present study to formulate the tablet form of *commiphora mukul* (guggil-100) and evaluate the preformulation characterization of a guggil-100 physical, chemical, and mechanical properties are involed the other ingredients should be used for the preparation. Formulation studies then consider such factors as pH, moisture, disintegration, friability, dissolution, particle size, polymorphism and solubility, as all of these can influence bioavailability and hence the activity of a guggil-100. In addition that to evaluate the extractive values and microbial load on the guggil-100.
Keywords: Guggil, commiphora mukul, pH, pharmaceutics, drug.

INTRODUCTION

The need to understand in more depth functional properties of materials used in pharmaceutical preparations, including their manufacturability, and to develop methods of analysis of such properties is growing [1]. Two streams of natural systems of medicine in India have been percolated through centuries till today. The first stream of natural medicine is based on an empirical experience with various kinds of herbs as regards to their healing abilities such usage has no logic on the nature of a specific biological activity. An approach of medicine is termed as ethno medicine; as such health care practices are mostly limited to specific ethnic communities. The other stream of natural medicine is scientific with an objective to expand the therapeutic resources within the nature it tries to understand the logic that govern the clinical or biological activity of various agents. Its approaches are aimed at the propagation of a scientific evaluation of empirical experience rather than spreading a mere belief on a particular remedy. This stream of natural medicine is termed as Ayurvedic [2, 3]. These measures while ensuring that the drug is free from contaminates also avoid direct worker contact with pharmacologically active and thus hazardous substances. Daily exposure threshold values (TLV) have been set to ensure worker protection. Threshold values have been arbitrarily set at 1:100 of the lowest pharmacologically active dose bearing in mind that the minimum effective dose was calculated on the basis of conventational drug administration and not resulting from exposure. In drug production, microbiology laboratories prepare samples of known origin hence simplifying acceptance procedures and sample opening. Special care is paid in avoiding secondary contamination of samples as the identification of even a single colony-forming unit on production area samples may be significant for certain production departments. Guggul lipids have been know to relive couhing and lung congestion, smooth mucous membranes and alleviate other respiratory problems. Guggul lipid may also be used to treat arthritis and reduce inflammation of the joints. A small controlled tiral compared oral guggulipid against tetracycline for the treatment of acne, and reported equivalents results. (www.indo-world.com).

MATERIALS AND METHODS

DRUG PREPARATION

100 gm of *commiphora mukul* extract, methyl paraben (70 mg), propyl paraben (35 mg), microcrystalline cellulose (20 gm), sodium benzoate (1 gm), talc (1.4 gm), starch (35 mg). Dissolution medium: 750 ml of distilled water, 750 ml of N/10 Hcl. methyl paraben, sodium benzoate and propyl paraben is used as a preservative agents, starch is used for binding agent. N/10Hcl preparation for 27ml of conc. Hcl was dissolved in 3liters distilled water and mixed well.

TABLET FORMULATION

The objective of the design and manufacture of the compressed tablet is to deliver orally, the correct amount of drug in the proper form, at or over the proper time and in the desired location and to have its chemical integrity protected to that point. Aside from the physical and chemical properties of the medicinal agents to be formulated into a tablet, the actual physical design manufacturing process, and complete chemical makeup of the tablet can have a profound effect on the efficacy of the drugs being administered. The manufacturing process of tablets involved in the following aspects.

DRYING

Guggul (100 gm) was dried in an oven at 40 degree for 3 hrs and the weighed recipients are microcrystalline cellulose (20 gm), methylparaben (70 mg), propylparaben (35 mg), sodium benzoate (1 gm), talc(1.4 gm), starch (35 mg) are dried for 3 hrs at 60 degree. The removal of liquid material in the drug, application of heat and is accomplished by the transfer of liquid from a surface into an unsaturated vapor phase. Drying is used to reduce bulk and weight there by lowering the cost of transportation and storage.

MIXING

To process that tends to result for randomization of dissimilar particles within a system. The recipients are microcrystalline cellulose (20 gm), methylparaben (70 mg), propylparaben (35 mg), sodium benzoate (1 gm), talc (1.4 mg), starch (35 mg) and above the recipients are mixed with guggul (100 gm).

GRANULATION

After mixing the mixture add some amount of water, mixed gently. Take 18 mm sieve, in that add the mixture and sieved smoothly. After sieving a small granule is formed, the granules are dried without moisture condition. After drying add of talc powder (5gm) and mixed gently.

PUNCHING

Tablet formulation by using Khera Motorized single punch tablet compression machine to put the lubricated granules in the die cavity and set the pressure at the minimum. Operate the machine by hand and observe the hardness of the tablet. Increase the pressure, if the hardness is sufficient. Once the correct pressure is achieved switch on the motor and continue tablet compression by placing all the granules in hopper. The process is continued till the granules exhausted.

TABLET COATING

The coating of tablets is the additional step in the manufacturing process ,increases the cost of product coating is used to mask, the taste ,odor or color of the drug .To provide physical and chemical protection for the drug .to control the release of the drug from the tablet.

FILM COATING

Film coating adhere to all exposed surfaces, so that any surface imperfection is coated and not eliminated. The quality of thin film coating is applied to compressed tablets usually depends much more on the quality of the starting tablet than on the time at which sugar coatings are applied. 9 gm of opadry green was transferred into a conical flask. To add 52 ml of isopropylalochol and stirred well by magnetic stirred. Again 59 ml of dichloromethane is added in a same conical flask stirred well and transferred the mixed solution into a coating pan and switch on the instrument. Spray the solution uniformity until got uniformity; uniformity is identified by weight variation.

ANALYTICAL PARAMETERS

AVERAGE WEIGHT OF A TABLET

A tablet designed to contain a specific amount of tablet formula, the weight of the tablet being made is routinely measured to help ensure that a tablet contains the proper amount of drug, average weight there could be tablets excessively over weight. To help alleviate this problem United States Pharmacopiea (USP)/National Formulatory (NF) provides limits for the permissible variations in the weight of the individual tablets expressed as a percentage of the average weight of the sample. The average tablet is close to the theoretic average weight. Composite samples of tablets (20) are taken and weighed throughout the compression process. The composite weight divided by 2. However it provides an average weight of a tablet.

UNIFORMITY OF A TABLET

In tablets with smaller dosages, a good weight variation dose not ensures good content uniformity, but a large weight variation precludes good content uniformity. To assure uniform potency for tablets of low dose drugs a content uniformity is applied for the randomly selected 50 numbers of tablets and at least 10 of them are assayed individually. Then 9 numbers of the tablets must contain not less than 85 % or more than 115 % of the tablet.

PH

Weighed quantity of sample dissolved in boiled cooled water and allowed to stir for 10 minutes. Filtered, the filtrated solution is determined by using PH meter. The PH is defined as the negative logarithm of

hydrogen ion concentration. PH was determined by using PH meter.

MOISTURE

The percentage of active chemical constituents in crude drug is mentioned on air dried basis. Hence the moisture content of a drug should be determined and also be controlled. The moisture content of a drug should be minimized in order to prevent decomposition of crude drugs either due to chemical change or microbial contamination. About 1gm of drug is accurately weighed and placed in a LOD dish. The moisture content was determined by heating a drug at 105 degree in an oven to a constant weight.

FRIABILITY

To perform this tablet is placed between two anvils, force is applied to the anvils and the crushing strength that just causes the tablet to break is recorded. These tablet hardness has carried for the force required breaking the tablet in a diametric compression test that friability.

DISINTEGRATION

A generally accepted maximum is that for a drug to be readily available to the body, it must be in solution. For most tablets the first important step toward solution is breakdown of the tablet into smaller particles or granules a process is known as disintegration. Place the water in the cylinder to a depth of not less than 15 cm and raise the temperature to 36-38 degree. Check that when the basket moves up and down the gauze just breaks the surface of the water at the highest position and that the rim of the basket remains just above the surface of the water at the lowest position. Place five tablets in the basket and set the basket in motion. Note the time and proceed with test until no particle. If the tablets fail the test it may be repeated using a guided a disc in the basket above the tablets. The guided disc of weight 2.0-0.1 g and carefully controlled dimensions fits neatly into the basket. The disintegration time was noted at after 15^{th} day on the stored by the different container and 45 º C temperature conditions.

DISSOLUTION

Tablet dissolution is a standardized method for measuring the rate of drug release from a dosage form the principle function of the dissolution may be the optimization of therapeutic effectiveness during product development and stability assessment. Dissolution was carried out by using two mediums. To place the 750 ml of N/10 Hcl or distilled water in a beaker and maintained the temperature at 37 ºC degree and place the tablet to be studied in the wire mesh basket and normally a speed for 50 rpm the samples placed at time 30, 60 minutes and maintains the volume constant by adding N/10Hcl or water after each removal of sample observed under UV spectra.

PARTICLE SIZE

The particle size analysis is to determine the particle size of the guggil-100 tablet. To take 20 mg of the both binding and without binding sample was mixed with the insoluble medium and stirred well. The sample should be uniformly dispersed in given solvent. The medium, kept in the conical flask is taken in by the syringe and it passes through the sensor by using particle size analyzer (Accusizer model 780). Few drops of the sample are added to the conical flask which is constantly stirred by the magnetic stirrer. The detector detects the number of particles per ml of the sample. The result derived was calibrated with reference to the baseline correction value. A data file can be retrieved to display the resulting particle size distribution with the desired weighing result.

ULTRA VIOLET AND VISIBLE SPECTROSCOPY

UV or visible radiation was passed through a substance under examination. Absorption of energy results in the promotion of electron from the ground electronic state to the excited state. During the process of absorption, a large number of photon-molecule collisions are possible but only these collisions will cause absorption of energy in which the photon matches the energy difference between the ground and excited electronic state of the molecule absorption of energy is quantized. In uv and visible spectroscopy electronic transition takes place. UV is the electronic spectroscopy since it involves the promotion of electrons from the ground state to the higher energy state.

STABILITY TEST FOR EXTRACTIVE VALUE:

This method determines the amount of active constituents in a given amount of medicinal plants material when extracted with solvents. It is employed for that material for which no chemical or biological assay method exists. As mentioned in different official books the determination of water soluble and alcohol soluble extractives is used as a means of evaluating crude drugs which are not readily estimated by other means

WATER SOLUBLE EXTRACTIVES

0.41 g of the dried powder of *commiphora mukul* was added in 50ml distilled water in a 250ml conical flask. It was shaken well and allowed to stand for 18hrs, thereafter it was filtered. 10ml of filtrate was transferred to 50ml beaker, the solvent was evaporated on a water bath and it allows drying for 30 minutes and then residue was weighed. Percentage of water soluble extractives was calculated.

ALCOHOL SOLUBLE EXTRACTIVE VALUES

0.41 g of the dried powder of *commiphora mukul* was added in 50ml ethanol in a 250ml conical flask. It was shaken well and allowed to stand for 18hrs, thereafter it was filtered. 10ml of filtrate was transferred to 50ml beaker, the solvent was evaporated o a water

bath and it allows drying for 30 minutes and then residue was weighed. Percentage of alcohol soluble extractives was calculated. Finally stored different extractive values are checked the stability test at 15th day

CONTAINERS

Glass is commonly used in pharmaceutical packaging because it possesses superior protective qualities, it is economical. Colored glass, especially amber can give protection against light when it is required. Amber glasses are effective in protecting the contents of a bottle from the effects of sunlight by screening out harmful UV rays s amber glass meets these specifications, but the iron oxide added to produce this color could into the product.

MICROBIAL LOAD

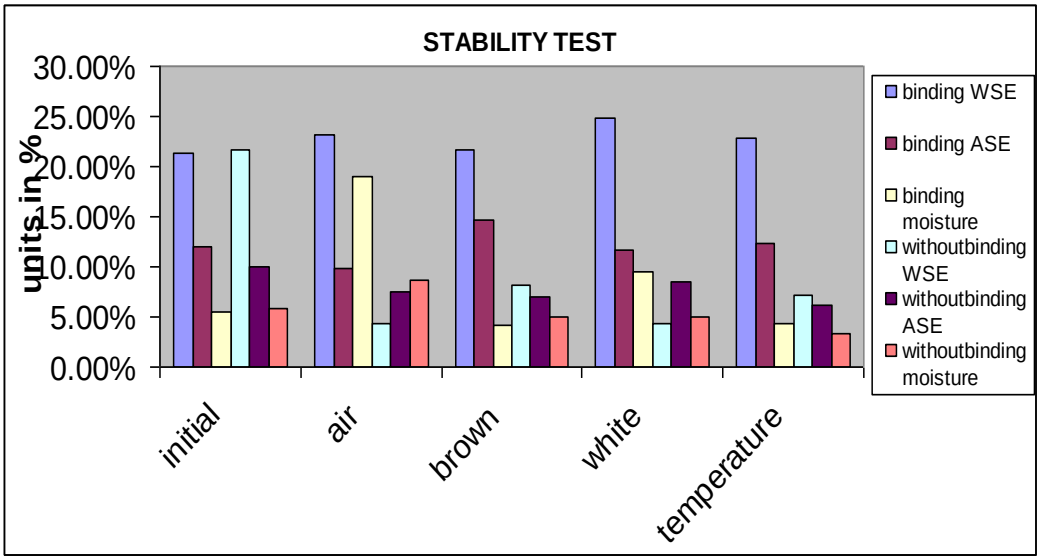
1gm of drug is weighed and added to 99ml of sterile distilled water for preparing the serial dilution. The samples in the flask were kept in a mechanical shaker for few minutes to obtain uniform suspension of microorganisms. The dilution is 1:100 or 10^{-2}. From that 1ml of the 10^{-2} dilution was transferred to 9ml of sterilized distilled water. This is 1: 1000. This procedure was repeated up to 10^{-6} dilution. 0.1 ml of serially diluted samples was inoculated to the sterile plate containing Nutrient agar, Salmonella Shigella Agar (SSA) and Potato Dextrose Agar (PDA) Medium by spread plate method. Nutrient agar and SSA plates were incubated at 37 ºC for 24 hours and PDA plates were incubated at room temperature for 3-5 days. Bacterial and fungal colonies were counted using colony counter. *Salmonella, Shigella* and *E.coli* can be counted using SS Agar medium.

RESULT AND DISCUSSION

The methanolic extract of *Commiphora mukul* purchased from ELLESS AROMATICS, Chennai. This study the extract was using different recipients for the drug preservation by using methyl paraben and propyl paraben. Then the binding agents such as starch and microcrystalline cellulose were applied for the substance that makes a loose mixture stick together with guggul (www.cancer.gov). After the granulation of the gugglu by using talc powder to form a granules by binding the powders together with an adhesive, instead of by compaction. The *Commiphora mukul* extract should formed by using 10/32 inch compressed machine and tablets were found. The average weight of the tablets by which adding the binding agents to increased the weight of the tablets, but without binding tablets as to be normal weight. The pH of the binding (pH 7.28) and without binding (pH 7.14) tablets was almost same, there is no change between them. The stability test involves the comparison of water soluble and alcohol soluble extractives, due to the addition of binder the stability of the drug has increased when compared to without binding tablets, the extractives values are represented in **Table 1**. The water and alcohol soluble extractives best in brown container and the condition of temperature at 45ºC should also good in alcohol soluble extract **(Graph 1)**.

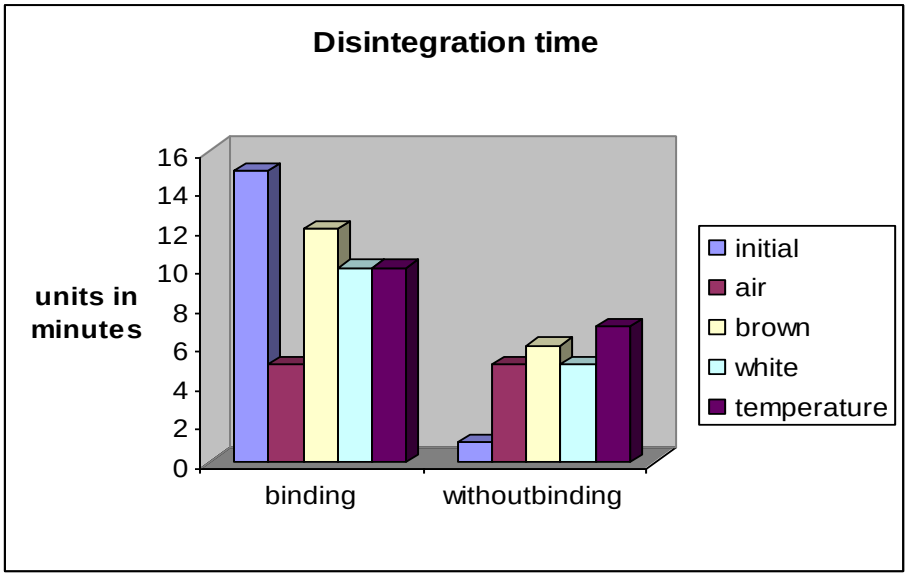
Table-1: Quality control test for guggil-100 tablet (with and without binding)

	Stability test						**Disintegration test**	
Content	Binding			Without binding			Binding	Without binding
	Water Soluble Extract %	Alcohol Soluble Extract %	Moisture %	Water Soluble Extract %	Alcohol Soluble Extract %	Moisture %		
Initial	21.2701	12.000	5.4521	21.6397	10.000	5.8000	15 min	1 min
Air	23.1660	9.8758	19.0175	4.3565	7.5829	8.6298	5min	5 min
Brown container	21.6996	14.6654	4.1893	8.2481	6.9239	4.9573	12min	6 min
White container	24.8070	11.7481	19.4614	4.2725	8.5450	5.0199	10min	5 min
Temperature	22.8158	12.2987	4.3565	7.1658	6.2215	3.2625	10min	7 min



Graph-1: Stability test for binding and without binding Guggil-100 tablet

The stability test **(Graph 1)** showed that Guggil-100 tablet containing at brown and temperature container best compare to others because the percentage of the moister expose good when compare to other container. Stability evaluation of drug substances and products is the key to drug quality as it determines the efficacy of any drug or its dosage form. Regular testing of drug stability is, therefore, considered to be the only way to ensure delivery of right therapeutic values to the patients during a treatment phase (www.pharmabiz.com). The disintegration time is noted in order to avoid interference in metabolic pathway of the system, the disintegration time for binding takes place more time due to the addition of binder, for without binding it easily disintegrates. Disintergration time showed **(Graph 2)** the time of the binding tablets over all increased in all containers when compare to without binding tablets, binding tablets are good in condition but specifically brown container was 12 minutes dehydrate after 15th day **(Table 1)**. The time required for a tablet to break up into granules of specified size (or smaller), under carefully specified test conditions. The conditions of the laboratory test, in vitro, are set to simulate those that occur in vivo. Factors such as the kind and amount of tablet binders and the degree of compression used in compact the tablet ingredients help determine disintegration time. The active ingredients in a disintegrated tablet are not necessarily found to be in solution and available for absorption. A long disintegration time is incompatible with rapid drug absorption; a short disintegration time, by itself, does not ensure rapid absorption.



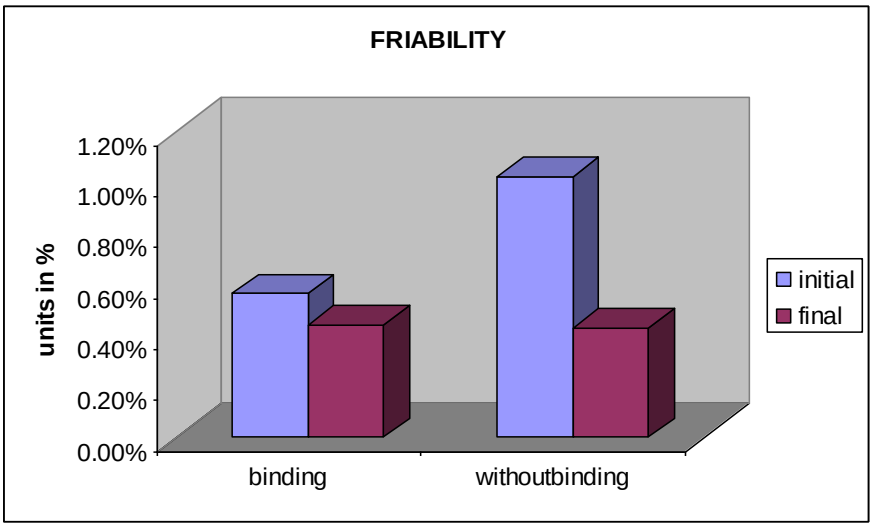
Graph-2: Disintegration Time for binding and without binding Guggil-100 tablet

Initial value of friability test in without binding tablet and to compare with binding tablet the breaking capacity increased in the tablet. So the addition of the binder to the tablet should prevent the damage of tablets

(Table 1). The main purpose of this test is to determine the relative strength of the diamond particles. The core of this test is to determine the particle size after the material is subjected to control crushing (www.lieberandsolow.com).

Table-2: Quality control test for guggil-100 tablet (with and without binding)

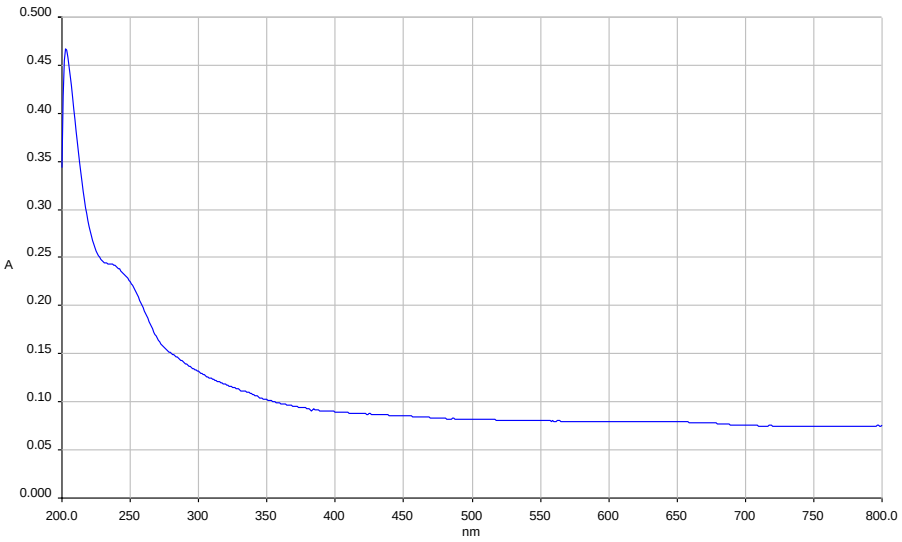
Description	Friability test	
	Binding	**Without binding**
Initial value	0.5629	1.0232
Final value	0.4408	0.4306



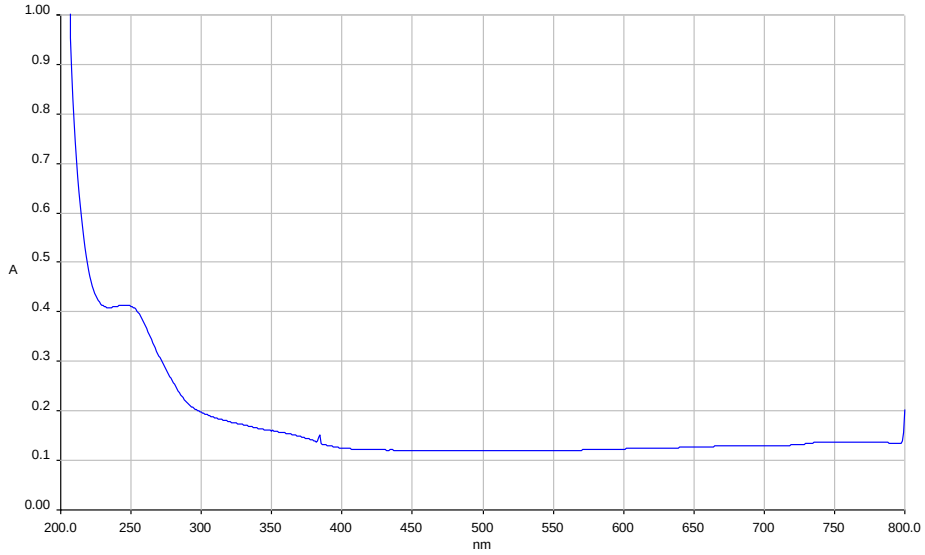
Graph-3: Friability test for binding and without binding Guggil-100 tablet

The **Graph 3** shows the strength of the tablets tested on the binding and without binding tablets, when compare to binding tablets, without binding tablets was less strength in friability test.

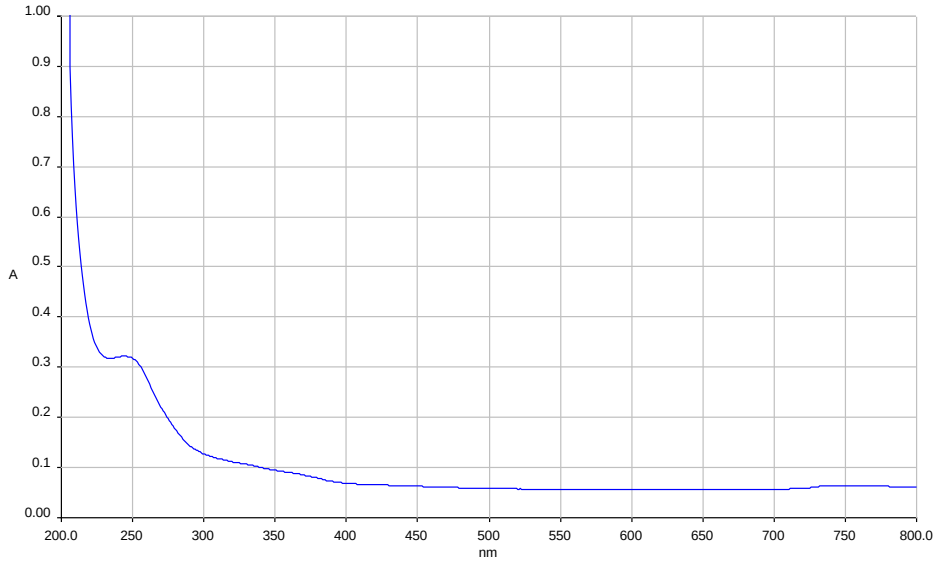
Dissolution test are more valid indicators of bioavailability than are disintegration. To determine the absorbance of raw extract as a standard used by brand sample over the region between 250 to 800 nm and calculate this amount of *comiphora mukul* (gugglu) was absorbance at 254 nm from one hour. The standard should compare with binding and without binding guggil-100 tablets were obtained as same 254 nm. The absorption of standard and sample in UV spectrum shows a minimum peak at around 254 nm. The observed spectral data provides an interesting feature that gugglu has a good dissolution rate in acid acid medium when compared to water and also denote the content of guggul distribution in each tablet (Graph 4-9).



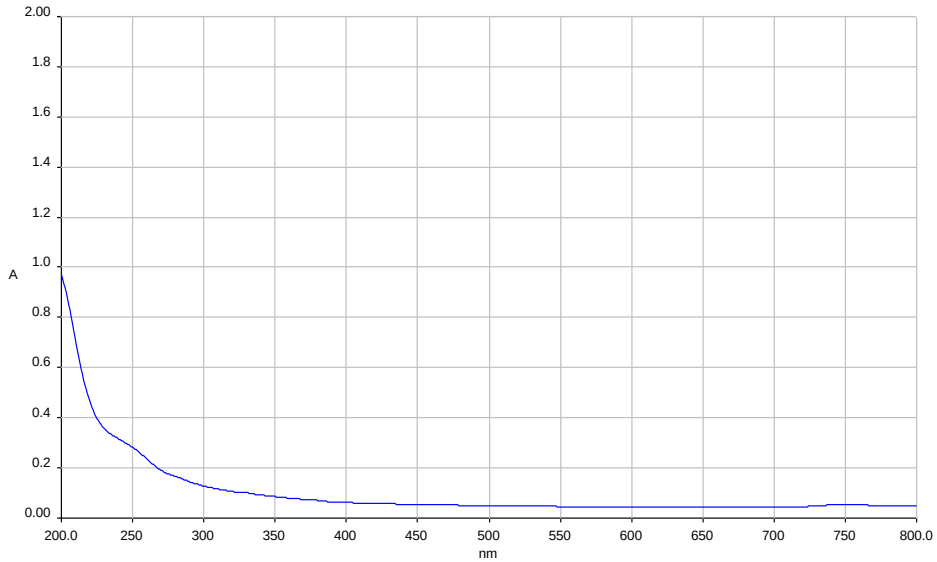
Graph-4: Dissolution rate by UV spectrum graph for standardization using acid



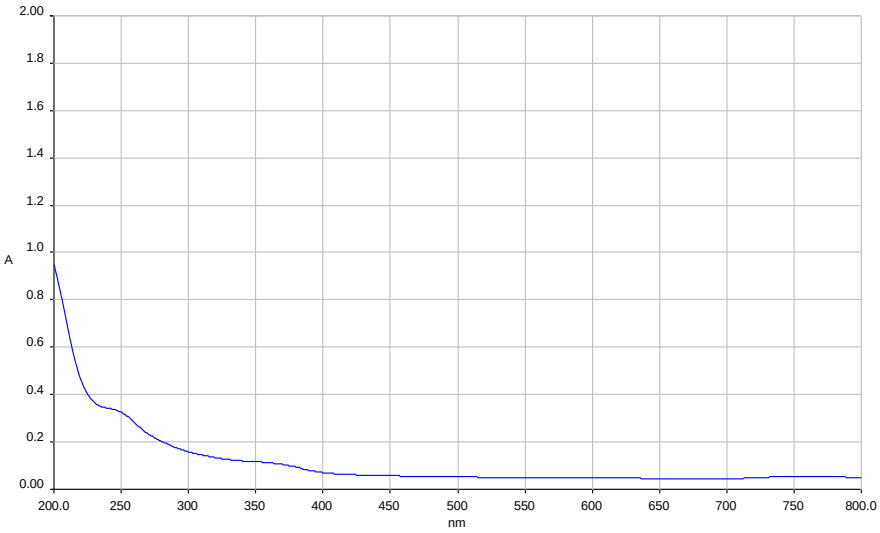
Graph-5: Dissolution rate by UV spectrum graph for binding tablets using acid medium



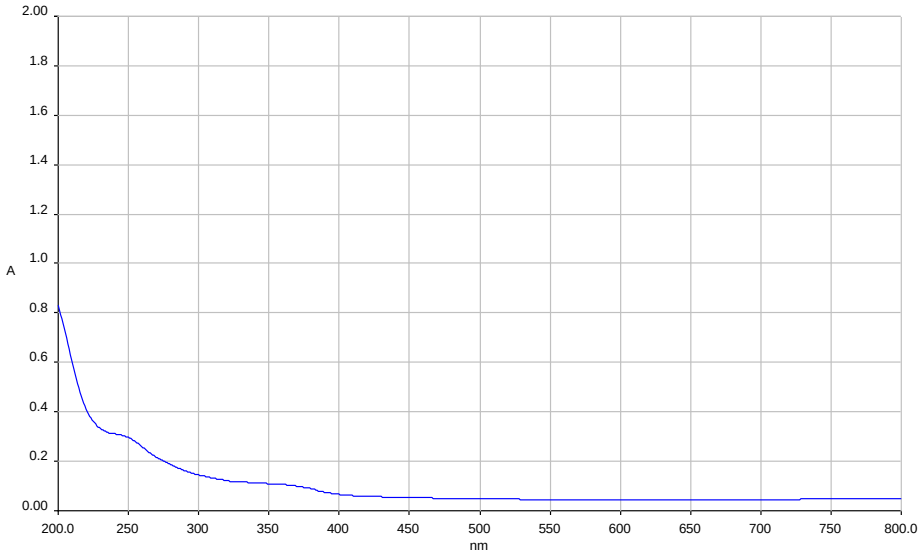
Graph-6: Dissolution rate by UV spectrum graph for without binding tablets using acid medium



Graph-7: Dissolution rate by UV spectrum graph for standardization using water



Graph-8: Dissolution rate by UV spectrum graph for binding tablets using water



Graph-9: Dissolution rate by UV spectrum graph for without binding using water

PARTICLE SIZE

The samples gugglu with binder and without binder were subjected to size analysis. The average mean weight of with binding 19.99 µm and the average mean weight of without binding 13.92um. The graphical representation of both the gugglu samples shows more or less the same result, yet the distribution value was slightly altered due to addition of starch granules. The distribution of 5 % value of gugglu with binding values 4.76 µm and that of without binding is 1.22 µm. The smallest particles were lower concentration and them completely different in both the samples. The different of the values represent the starch granules which may be 3.54 micron. The distribution of 50 % value of gugglu with binding 12.25 micron and that of without binding is 8.94 micron. The difference of this value was 3.31 micron which is nearly similar to the distribution 5 % values. But when we take distribution 99 % values both the results are 157.05 micron, so this result attributes only to the size of the gugglu particles and dose not represent values of starch particles. From this we could understand that the gugglu with binder (starch particle) doesn't alter the population cumulative distribution of the drug bioavailability to the body. The microbial load for the plant *commiphora mukul* and extracts were identified and they were found to be within the limit of WHO limits. The results were given in table in 1& 2. Based on our investigation, the results found in both raw material as well as extracts for microbial load contains within the permissible limit of WHO standards.

Table-3: Microbial Load for binding Guggil-100 tablet

S.No	Bacterial Name	Sample Name	WHO Limit	Cells in Sample/g	Interference
1.	*E.coli*	*Commiphora mukul Raw Material*	10^2	2 X 10^1	Fair
2.	*Salmonella sp.*		Absence	-	
3.	*Shigella sp.*		Absence	-	
4.	*Enterobacter sp.*		10^4	-	
5.	Total Heterotrophic Bacteria		10^7	12 X 10^2	Fair
6.	Yeast & Mould		10^4	1 x 10^2	Fair

Table-4: Microbial Load for without binding Guggil-100 tablet

S.No	Bacterial Name	Sample Name	WHO Limit	Cells in Sample/ g	Interference
1.	*E.coli*	Commiphora mukul *Extract*	10^2	-	Good
2.	*Salmonella sp.*		Absence	-	Good
3.	*Shigella sp.*		Absence	-	Good
4.	*Enterobacter sp.*		10^4	-	Good
5.	Total Heterotrophic Bacteria		10^7	10X 10^1	Fair
6.	Yeast &Mould		10^4	-	Good

CONCLUSION

In this study evaluate the herbal drug by using modern techniques to promote the quality of the drug should follows the basic determines for the marketing.

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