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"Formulation and Evaluation of Anti haemorrhoid Tablet From Abutilon Indicum leaves"

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ABSTRACT: Abutilon indicum (**Indian abutilon**, **Indian mallow**)isa small shrub in thefamily Malvaceae, native to tropical and subtropicalregions.This plant is often used as a medicinaland ornamental plant,. It has been widely introduced outside of its native range, and is considered invasive on certain tropical island. To formulate Anti-hemorrhoid tablet from AbutilonIndicumLeaves. Abutilon indicum (Linn.) Sweet is astringent and bitter in taste, odorless in odor and green in colour. Powder microscopic study of roots powder of Abutilon indicum (Linn.) Sweet revealed Fiber, Calcium Oxalate crystals and Starch grains, Cork cells after observation under microscope. Loss on drying is a water holding property of test substance.Moisture content and pH value was found to be 4.45% and 5.5. Extractive value is directly relative to strength or potency of drug which estimates in different solvents.. Ash value is the indicator of the presence of inorganic and earthy matter in theplant. It was found the tapped density 1.14, Hausner Ratio 1.17 Indicates good flow properties while >1.5 indicate properties flow of powders, angle of repose 10.93,Carr's Index 11.83%, ash value 0.24g, The Drug Abutilon Indicum Is completely soluble in Alcohol, sprangly soluble inconc. Hcl.

Objective: Abutilon indicum is an ethnomedicinal plant that has several medicinal claims and it hasn't been exploredthoroughly.

Various parts of the plant are used medicinally such as demulcent, aphrodisiac, laxative, diuretic, pulmonary disorders,etc.

The aimed to evaluate the leaf extracts of Abutilon indicum for acclaimed anti- diarrhoeal activity.

Aim of this study is to analyze the antibacterial and antioxidant potential of crude saponin extract (CSE) from Abutilon indicumleaves.

Keywords: AbutilonIndicum, Pre-formulation and Evaluation studies, Anti hemorrhoid

I. INTRODUCTION

Piles is another term for haemorrhoids (मुळव्याध).

Haemorrhoids are collections of inflamed tissue in the anal canal. They contain blood vessels, support tissue, muscle, and elasticfibre.

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- Piles are collections of tissue and vein that become inflamed andswollen.
- The size of piles can vary and they are found inside and outside of theanus.
- Piles occurs due to chronic constipation , chronic diarrhea, lifting heavy weights, pregnancy, or straining when passing astool.

Many people have piles, but the symptoms are not always obvious. Hemorrhoidscause noticeable symptoms for at least 50 percentof people in the United States (U.S.) before the age of 50 years. Piles are inflamed and swollen collections of tissue in the anal area.

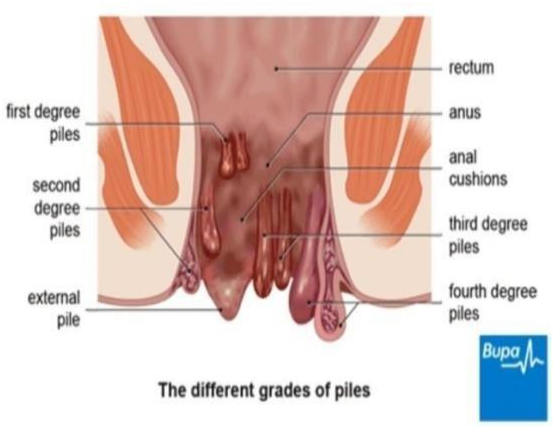
1.1 TYPES OFPILES:-

There are main Two Types of Hemorrhoids Or Piles VIZ.

- ExternalHemorrhoids
- InternalHemorrhoids

Upon these Classification Piles are Classified into Four Grades.

- Grade I: There are small inflammations, usually inside the lining of the anus. They are notvisible.
- Grade II: Grade II piles are larger than grade I piles, but also remain inside the anus. They may get pushed out during the passing of stool, but they will returnunaided.
- Grade III: These are also known as prolapsed hemorrhoids, and appear outside the anus. The individual may feel them hanging from the rectum, but they can be easily re-inserted.
- Grade IV: These cannot be pushed back in and need treatment. They are large and remain outside of theanus.



The different grades of piles

1.2 SYMPTOMS OFPILES:-

Piles don't always cause pain or other symptoms, but if you do have symptoms, they might include: The symptoms of the hemorrhoids (piles) differ when they are formed in a different location.

- bleeding when you poo – you may see blood (usually bright red) on toilet paper or drips in the toilet or on the surface of yourpoo.
- a lump in or around youranus.
- a slimy discharge of mucus from your anus, which may stain yourunderwear.
- a feeling of 'fullness' and discomfort in your anus, or a feeling that your bowels haven't completely emptied after you've gone to thetoilet.
- itchy or sore skin around youranus.

pain and discomfort after you go to the toilet.

1.1 Causes:-

Piles are caused by increased pressure in the lower rectum..

The blood vessels around the anus and in the rectum will stretch under pressure and may swell or bulge, forming piles. This may be dueto.

- chronicconstipation
- chronicdiarrhea

1.3 Treatments:-

In the majority of cases, piles resolve on their own without the need for any treatment. However, some treatments can help significantly reduce the discomfort and itching that many people experience with piles.

Following are some Minor Treats that Helps to controls the piles.

- **Diet**:

Piles can occur due to straining during bowel movements. Excessive straining is the result of constipation. A change in diet can help keep the stools regular and soft. This involves eating more

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fiber, such as fruit and vegetables, or primarily eating bran-based breakfastcereals.

- **Body weight**: Losing weight may help reduce the incidence and severity of piles. To prevent piles, doctors also advise exercising and avoiding straining to pass stools. Exercising is one of the main therapies for piles.
  Several medicinal options are available to make symptoms more manageable for an individual with piles.such as.

1. Over the CounterMedications
2. Corticosteroids
3. Laxatives
4. Banding
5. Sclerotherapy
6. Infrared Coagulation

Monograph Sheet of Atibala (Abutilon Indicum)

-Botanical Name	**Abutilon Indicum**
Geographical Source	The Plant is found in India, Shri-Lanka. Tp[oca; region of Amerika an Malesia it is found as a weed in Sub Himalayan tracts.
Synonym	Abelmoschus Mallow or Indian Mallow or Sida Indica
Family	Malvaceae
Order	Malvalic
Kingdom	Plantae
Chemical Formula Or Imperical Formula	C17H14O7
Chemical Name OR IUPAC	3,5,7 try Hydroxy, IV, 6 Dimethoxy Flavone
Category	MAGNOLIOPSIDA - Dicotyledons
Description	A) Macroscopic= Leaf,Shape-Cordate Size-2.4 cm long Color-Green Odour-Characteristics Test-Characteristics B) Microscopic:- Leaves were observed as covering trichomes, glandulartrichomes,Vascularbundles , Lateral Vein, Crystals,Stomata, SpongyMesophyll.
Solublity	The Drug Abutilon Indicum is completely Soluble in Alcohol and Sprangly in Concentrate HCL
Ash Value	0.25 gram
Functional Category	AmideGroup,phenolic Group, Either ETC.

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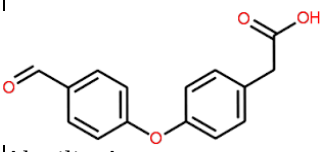
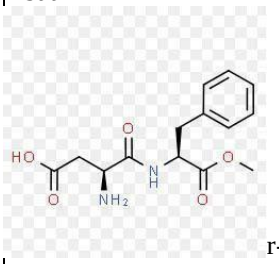
Chemical Nature	A) Anti-oxidant B) Antifungal C) Analgesic D) Anti-Diarrhea E) Demulcent F) Diuretic G) Lipid-lowering
Moisture Content	3.2 % yield

Storage Condition	Flowering is Temperature and light dependent Anthesis occurring At 25-30^0 C
Chemical Structure	 Abutilin-A=  r-n-(1- - methoxy n-(1-methoxycarbonyl-2-phenylethyl
Chemical Constituent	A) Abutilon-A= B) R-n(1-- methoxyn-(1-methoxycarbonyl-2- phenylethyl C) Alnath-lactone D) GallicAcid E) Beta-Sitosterol F) Eugenol
Density	The Density of Extract of Leaves Of Abutilon Indicum Was Measured Spectrophotometrically at 650 nm
Molecular Formula	A) Abutilon A =C15H12O r-n-(1- B) - methoxyn-(1-methoxycarbonyl-2-phenylethyl= $C_{17}H_{17}NO_4$
Flowability	The directly compressible adjuvant should be free flowing. Flowability is required in case of high-speed rotary tablet machines, in order to ensure homogenous and rapid flow of powder for uniform die filling.Duringthe short dwell- time (milliseconds), the required

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	amount of powder blend should be transferred into the die cavities with reproducibility of + 5%.

Ingredients	Imperial Formula	Molecular Weight	Melting Point	Boiling Point	Synonym
Magnesium Stearate	C36H17MgO4	591.34	117-150^{0}C	359.4^{0}C	MagnesiumOctadic
Talc	Mg6(si2o5)4(oh)4	379.27	1500^{0}C	Above 900^{0}C	Hydrous Magnesium ,Silicate.
MacrocrystallineCellulose	C6H10O5	36000	482^{0}F	667.9^{0}C	Avicel ph.
Starch	C6H10O5	105	256-258^{0}C	667.9 + 55^{0}C	Word hippoThesaurus
Lactose	C12h22O11H2O	36031	202.8^{0}C	668.9^{0}C	Carbohydrate

II. MATERIALS AND METHODS :

Ideal requirements of Tablet By direct CompressionMethod:-

The tablets are manufacture by Following Two methods viz,

A) Wet Granulation method.

B) Dry granulation Method Orslugging.

Tablet should possess the following ideal properties to be compressed by direct compression method.

a) Flowability:-

The directly compressible adjuvant should be free flowing. Flowability is required in case of high-speed rotary tablet machines, in order to ensure homogenous and rapid flow of powder for uniform die filling.Duringthe short dwell-time (milliseconds), the required amount of powder blend should be transferred into the die cavities with reproducibility of + 5%. Many common manufacturing problems are attributed to incorrect powder flow, including non-uniformity in blending, under or over dosage and inaccuratefilling.

b) Compressibility:-

Compressibility is required for satisfactory

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tableting i.e. the mass must remain in the compact form once the compression force is removed. Few excipients can be compressed directly without elastic recovery. Hence the directly compressible diluent should have good compressibility i.e. relation between compaction pressure and volume.

c) Dilution potential:-

Dilution potential is defined as the amount of an active ingredient that can be satisfactorily compressed into tablet with the given directly compressible excipients.

A directly compressible adjuvant should have high dilution potential so that the final dosage form has a minimum possible weight. The dilution potential is influenced by the compressibility of the active pharmaceutical ingredient.

d) Re-workability:-

A directly compressible adjuvant should be capable of being reworked without loss of flow or compressibility. On recompression, the adjuvant should exhibit satisfactory tableting characteristics.

e) Stability:-

The adjuvant should remain unchanged chemically and physically and should not exhibit any physical or chemical change on aging and should be stable to air, moisture and heat.

f) Control of particleSize:-

A directly compressible adjuvant should have a particle size equivalent to the active ingredients present in the formulation in the formulation .The particle size distribution should be consistent from batch to batch. Reproducible particle size distribution is necessary to achieve uniform blending with the active ingredient(s) in order to avoid segregation.

Advantages Of Directcompression:-

a) High doses can be accommodated and final weight of the tablet can exceed that of othermethods.
b) Easiest way to manufacture thetablets.
c) Conventional equipment and commonly available excipients areuse.
d) A limited no. ofprocessing stepsisinvolved. Cost- effectiveness.

2.2) Pre-formulation studies of Drug:-

1) Organoleptic Properties:

The abutilon Indicumwas examined for its organoleptic Properties like Colour, Odour, Andapperance,etc.

2) Bulk Density:

Bulk Density was Determined by pouring the blend into a graduated Cylinder. The bulk volume(vb) and Weight of the powderwas
determined by, Bulk density =M/vb.

3) TappedDensity:-

The measuring cylinder containing a known mass of powder blend was tapped for fixed number of times as per USP apparatus ll. The minimum volume occupied by the powder after tapping was measured.

density=weight /Tapped volume.

F1	F2	F3	F4	F5
1.11	1.13	1.14	1.16	1.17

4)Hausner Ratio:

It is an Indirect Index of ease of powder Flow. It is calculated by , Tapped Density/Bulkdensity.
Hausner Ratio<1.25 Indicates good flow properties while >1.5 indicates poor properties flow of powders.

F1	F2	F3	F4	F5
1.11	1.13	1.14	1.16	1.17

5)Angle ofRepose:-

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The angle of repose is defined as the angle between surface of pile of powder to the Horizontal plane . The angle of repose Is Determined by using funnel method. The blend was poured through funnel that can rice through vertically untill the maximum cone of height(h) was obtained. Radius of pile (r) was measured and angle of repose was calculated by,

Angle ofrepose=Ø=tan−1h/r

F1	F2	F3	F4	F5
14.89°	12.03°	11.74°	10.93°	10.47°

6) Carr's Index:-compressibility is the ability of powder to decrease volumeunderpressure.Compressibilityisthemeasuredthatisobtained from density measurements.
%compressibility=Tapped Density-Bulk Density/Tapped density×100.

F1	F2	F3	F4	F5
9.90 %	11.50 %	12.28 %	13.80 %	14.52 %

Compressibility measures gives idea about flow property of granules as per CARR'S index ,the value between 5-15 % indicates excellent free flowing granules and 12-16 % shows good free flowing granules ofpowder.

7) Solubility:-The Drug Abutilon Indicum Is completely soluble in Alcohol, sprangly soluble inconc. Hcl.

8) Ash Value:-The ash values are helpful to determine the quality As well as purity of crude drugs especially when the drugs is present in flowing granules of powder form.

F1	F2	F3	F4	F5
0.30g	0.28g	0.25g	0.23g	0.22g

III. EVALUATION AND QUALITY CONTROL TEST OFTABLET:

1) Size andshape:-

For comparable ease of swallowing as well as patient acceptance and compliance with treatment regimens, the Agency recommends that generic oral tablets should not exceed 22mm.

For easy swallowing of tabletscare manufacturing on round and oval shape as patient acceptance.

2) Weight Variation:-Twenty tablets are weighed individually and the average weight is calculated . The individual tablets weight is compared to averageweight.

3) Hardness :--The resistance of tablets to capping, abrasion, or breakage under conditionsofstorage,transportationandhandling beforeusagedependsonits
hardness. The Monsanto or stokes hardness tester measures that force required to break the tablet when the force generated by a coil spring is applied diametrically to thetablet.
The hardness of Ant hemorrhoid tablet from abutilon indicum is 5 kg/cm2.

4) Thickness:--Tablet Thickness Is determined by the diameter of the tablet. Micrometer and vernier caliper are used for checking thickness oftablets.
Thickness should be controlled within +or -5%

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variation of the standard value. Thickness must be controlled for consumer acceptance of the product The thickness of Ant hemorrhoid tablet from abutilon indicum is 2.14 mm.

5) **Friability Test:**-It is usually measured by the use of the Roche Fabricator. A 20 tablets are weighed and placed in the apparatus where they are exposed to rolling and repeated shocks. After 100 revolutions the tablets are weighed and compared with the initial weight. The loss due to abrasion is the measure of the tablet friability. The value is expressed as the percentage.

6) **Disintegration Test:**-The disintegration test is measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles which will pass through a 10 meshscreen. The disintegration time for orally dispersible tablets for Anti hemorrhoid tablets from abutilon indicum leaves is 2.41 min.

7) **Dissolution test:-**

Dissolution rate of abutilon indicumfrom all formulations was performed using LABINDIA DISSO2000 an eightstage dissolution rate testing apparatus with paddle.

The dissolution fluid was 900 ml of PH7.2 of potassium dihydrogen phosphate buffer with a speed of 50 rpm and temperature of 37±0.5˚C were used in each test. 5 ml of sample was withdrawn at different time intervals (2.5, 5, 10, 15 & 20 mins) and fresh medium was replaced to maintain sink conditions. The samples are analyzed by using UV-Visible spectrophotometer at λmax 205nm.

Calibration curve of abutilon Indicum and it's absorbance in potassium dihydrogen phosphate buffer pH 7.2 at 205nm.

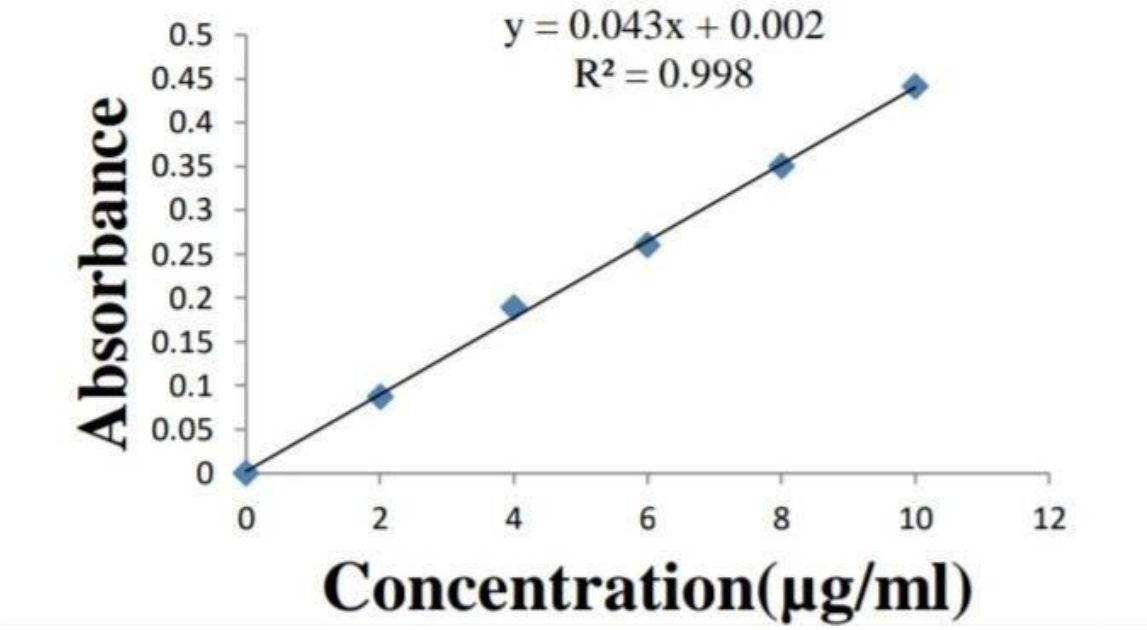

Fig1 Calibration Curve Of abutilon indictment 205 nm in potassium dihydrogen phosphate buffer pH7.2

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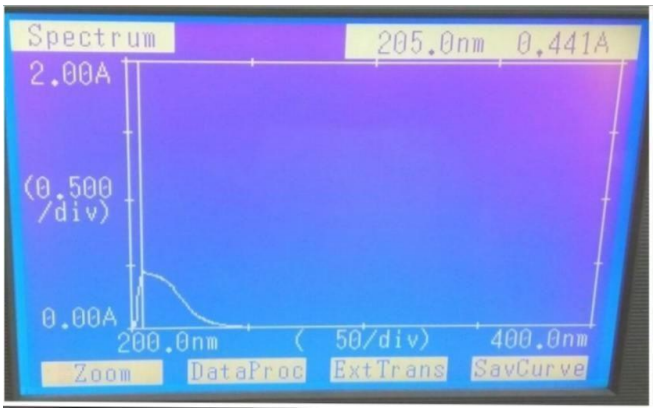

Fig- UV spectrum of Abutilon indicum

IV. OBSERVATION AND DISCUSSION

Pre-formulation	F1	F2	F3	F4	F5
Bulk Density/10ml	1	1	1	1	1
Tapped density	1.11	1.13	1.14	1.16	1.17
Hausner Ratio	1.11	1.13	1.14	1.16	1.17
Angle of repose	14.89°	12.03°	11.74°	10.93°	10.47°
Carr's index	9.90%	11.50%	12.28%	13.80%	14.52%
Ash Value	0.30g	0.28g	0.25g	0.23g	0.22g

Tests	Observations	Ip specification
Colour	Green	Complies
Taste	Bitter	Complies
Odour	Odorless	Complies.

Batches	F1	F2	F3	F4	F5
Thickness(mm)	2.24	2.18	2.20	2.25	2.23
Hardness(kg/cm2)	5.25	4.90	5.15	4.85	5.00

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Friability	0.15	0.23	0.28	0.17	0.19
Weight Variation(mg)	500	490	510	500	500

V. CONCLUSION

From the above research work it was concluded that herbal Antihemorrhoid tablet prepared in the form of cost effective tablet to minimize patients compliance in regarding suppressing side effects and enhancing positive effects on the body. The physiochemical property show satisfactory results by Ant hemorrhoid tablet which are within the range of prescribed standards required for investigation .

The extensive survey literature reviewed that Abutilon Indicum Linn, is an important medicinal plant with diverse pharmacological spectrum. some important pharmacological studies on hepatoprotective, wound healing, immunomodulatory, analgesic, an-malarial, antimicrobial, hypoglycemic activities of Abutilon Indicum .Due to medicinal properties there is enormous scope for future research on Abutilon Indicum and further clinical and pharmacological action. Abutilon Indicum have many more pharmacological properties like, the main chemical constituents are carbohydrates, steroids, glycosides, flavonoids, tannins andPhenolic compounds.

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