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"Preparation and evaluation of Anacyclus pyrethrum herbal mouth dissolving film"

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ABSTRACT

The wild species Anacyclus pyrethrum (A. pyrethrum), which is a member of the Asteraceae family and is utilised in traditional medicine. From review Numerous pharmacological effects of the plant have been noted, including Dysarthria ,antidiabetic, immunostimulating effect, inhibitory effect, antidepressant activity, anticonvulsantactivity, memory-enhancing activity, aphrodisiac, antimicrobial activity, antioxidant, local anaesthetic effect, insecticidal effect, , interactions with libido.So we mainly focus on the dysarthria activity of the Anacyclus pyrethrum .Goal of the study:-The research is done to prepare and evaluate herbal Mouth dissolving film to treat Dysarthria activity by using hydroalcoholic extract of root powder of Anacyclus pyrethrum.We prepare mouth dissolving film by solvent casting method .We perform the preliminary test for phytochemicals from which we found that Alkaloids and flavonoids are present .

Keywords :

Anacyclus pyrenthrum, Aqarqurha,unani medicine, Histopathology,Antiinflammatory,Analgesic,wound healing.

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CHAPTER 01 : INTRODUCTION

1.1 DESCRIPTION OF ANACYCLUS PYRENTHRUM

Figure 1.1 Anacyclus Pyrenthrum

It is a species of the Asteraceae family that is native to Algeria, Spain, and Morocco. Moroccans refer to it locally as "Aqar-qarha" or "Tigandizt." The scientific community has given the traditional use of medicinal plants as homoeopathic treatments for many illnesses its full attention. Anacyclus Pyrenthrum var Pyrenthrum (L) and Anacyclus Pyrenthrum var depressus(ball) maire are two variations of this species found in Spain. It has been noted that Anacyclus pyrethrum (A. pyrethrum) exhibits anticonvulsant properties. One finger's worth of root measures 2-4 inches long and is 1-2 cm thick. It is solid, dense, hard, and thick. It has a vertical groove on the outside and is brown in colour on the inside. Autumn is the ideal time to gather, dry, and store roots. The taste of Aqarkarha's roots is Charpara, which is astringent and bitter and causes the tongue to swell up when touched. The leaves are pinnately divided, radical, and petiolated, and one head branch. The bloom is white, and after eating, it causes salivation and a prickling feeling. The flower's attachment to the thalamus has a convex form. Pyrenthrum is prescribed or used to cure a variety of conditions, including tootaches, salivary secretion, digestive issues, angina pectoris, female infertility, lethargy, and even tongue and limb paralysis. They are also used to treat and prevent gout and sciatica in the form of animal fats with a cream basis. This plant plays a significant function in the digestive system, cosmetics, and is frequently used for the prevention and treatment of similar disorders due to its effectiveness and low side effects. The roots of this plant are suggested as a sialagogue for treating a variety of illnesses and diseases in conventional medicine. Drugs of mineral origin (Adviya Madniya) include different metals, metal ores, and non-metals in natural form, while drugs of animal origin consist of animal glands, tissues, physiological products, and pathological products.

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- history of use as a key medication for the treatment of Amrad Asab wa Dimag (disease of the nerve & brain), Amrad Asnan (disease of the teeth), Amrad Bah (sexual disease), and Amrad Khilt-i-balgham (phlegmatic disease), as mentioned in Unani literature. The phytochemical analysis of Anacylcus pyrethrum has shown a number of secondary metabolites, including tannins, flavonoids, coumarins, alkaloids, and reducing substances.Additionally, this species hastraces of essential oil,saponins, sesamin, inulin, and gum. Its root contains polysaccharides and N-isobutyldienediynamide, two of the most significant phytoconstituents.Moreover, the studies on the safety of its use were reported.

INTRODUCTION OF DYSARTHRIA

- Powder of this plant root mostly use in the Slurred speech (Dysarthria) **Dysarthria causes slurred or slow speech that can be difficult to understand**
- Signs and symptoms of dysarthria vary, depending on the underlying cause and the type of dysarthria. They may include:
- Slurred speech
- Slow speech
- Inability to speak louder than a whisper or speaking too loudlyRapid speech that is difficult to understand

MDF

- Fast mouth dissolving film drug delivery system have rapidly gained acceptance as an important new way of administering drugs .
- A film containing active ingredient that disolves or disintegrate in the saliva with in a few second without the need for water or chewing .

ADVANTAGES:-

- Good mouth feel
- Larg surface area promotes rapid disintegration and dissolution in the oral cavity .

DISADVANTAGE:-

- Drugs which are unstable at buccal pH cannot be administered.
- Drugs which irritate the mucosa or an obnoxious odor cannot be administered by this route.

Ideal characteristics

- The drug with smaller and moderate molecular weight are preferable.
- The drug should have good stability and solubility in water as well as in saliva.

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- It should have the ability to permeate oral mucosal tissue

OBJECTIVES

- To develop oral drug delivery system in the form of fast dissolving film which overcome first pass metabolism and the drug achieve to specific site for greater therapeutic action
- To help in strengthening muscle of toungue
- For rapid onset of action

Easy to use

1.1.2 TAXONOMICAL CLASSIFICATION

Kingdom	Plantae
Division	Spermatophyta
Sub-Division	Angiosperms
Class	Dicotyledons
Sub-Class	Metachlamydae
Order	Companulatae
Family	Asteraceae
Genus	Anacyclus

Table 1.2.1 Taxonomical classification

1..1.3 GEOGRAPHICAL DISCRIPTION

It is indigenous to Spain, Morocco, Algeria, the Middle East, North Africa, and Europe. It has been discovered that it can also be found in China's Xibjiang region and Central Asia. This species inhabits Morocco's hermes, cut forests, grasslands, low plains, middle, and high mountains, as well as cold, semi-arid, semi-humid regions at the Saharna Atlas level, against the Atlas High Atlas, North Atlantic Morocco, the plaeteau of eastern Morocco, and Rif at elevations between 1000 and 2500 m.

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1.1.4 PHYTOCHEMISTRY

-Chemical Compounds of the Essential Oils :

The essential oils (EOs) from A. pyrethrum have long been extracted in the literature using hydrodistillation. This species doesn't produce much EOs, and its yield isn't much more than 1%. Additionally, the flowering season is when it produces the most EO. A different study also discovered that the Timahdite (Middle Atlas) spontaneous species' EO output was substantially larger after flowering (0.07%) than before (0.05%). The species' EO yield in Algeria during the vegetative, floral, and post-flowering stages. This species doesn't produce much EOs, and its yield isn't much more than 1%. Additionally, the flowering season is when it produces the most EO. Spathulenol (20.47%),germacrene-D (16.48%), and caryophylleneoxide(13.20%) are the primary components. Caryophyllene-4(14), 4-(14)-salvial-1-one, and 8(15)-diene5-ol (7.30%). The most prevalent group of the discovered chemicals is the oxygenated sesquiterpenes. During the maturity stage, its rate fluctuates between 89.17% (before blooming) and 90.58% (after flowering). This category is also the most numerous species in Algeria, as seen in. The fraction of sesquiterpenes in this investigation was ranged before and after the flowering, respectively, between 37.1% and 58.6%.

- Non-volatile compounds

A. pyrethrum's chemical composition has been the focus of numerous studies. Alkaloids, reducing chemicals, and catechins tannins were discovered during the phytochemical analysis of the plant's leaves, flowers, roots, and flower heads. This species also includes trace amounts of trace minerals like Fe, Zn, Cr, Cu, Cd, Pb, and Ni as well as other compounds such gallic tannins, sterols, triterpenes, mucilage, coumarins, lipids, and holocides. Compared to the leaves and roots, the flowers have the largest concentration of flavonoids and polyphenols. Tannins are plentiful in the aerial parts while alkaloids are found in great quantities in the roots. The bioactive substances n-alkylamides and sharp brown resin, trace amounts of tannic acid, inulin, gum, different salts, anacycline, phenylethylamine, polyacetylenic amides I–IV, sesamin, and lignin are the most significant components found in the roots. A natural group of six chemically related esters, including three chrysanthemum acid esters (pyrethrin I, cinerin I, and jasmolin I) and three pyrethrins (pyrethrin II, cinerin II, and jasmolin II), make up the pyrethrins found in the roots.

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of pyrethrins 1 and 2, cinerin 1 and 2, and jasmolin 1 and 2, respectively. When pellitorin is isolated, a new crystalline compound is created that has a melting point of 121 °C, is sparingly soluble in benzene, and crystallises from chloroform-benzene in the form of white needles. Alkaloids, flavonoids, tannins, steroids, triterpenes, reducing sugars, oils, saponins,anthraquinones,and amino acids have been found in the ethanolic and aqueous extracts, the aqueous and methanolic extracts, and the ethanolic and aqueous extracts from the exposed roots. The n-alkylamides were the focus of a further qualitative and quantitative analysis of the A. pyrethrum methanolic extract because they exhibit distinct fractionation pathways that can serve as a foundation for the identification of the constituents in this plant. Four substances, 2,4-undecadin-8,10-diene-n-tyramide, levulinic acid, palmitic acid, and n-isobutyl-dodeca-2,4,8,10-tetra enamide, were found in A. pyrethrum var.depressus.

1.1.5 NUTRITIONAL VALUE

- Chemical constituents :

. phytochemicals like alkaloids, coumarins, flavonoids,and tannins are present in the anacycluspyrethrum variety.

. The root extract contains free fatty acids, sterols ,and unsaturated amides.

. Pellitorin, anacyclin, phenylethylamine, inulin, polyacetylenic amides and sesamin.

-Nutritional Benefits:

. Phytochemicals screening of akarkara shows the presence of carbohydrates, proteins, and amino ac

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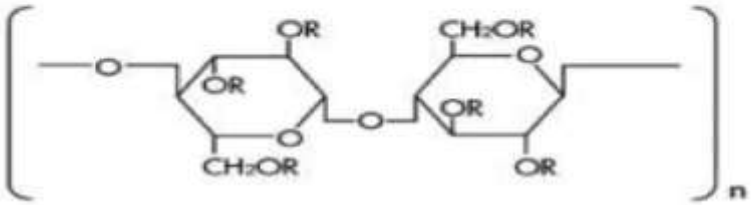
1.1.6 EXCIPIENT PROFILE

Polymer profile :- HPMC E-15

Hydroxyl propyl methyl cellulose

Structure:



R = -H
-CH_3
-$CH_2CH(CH_3)OH$
-COC_6H_4COOH

- **Synonym** : HPMC, Methocel, metolose, pharmacoat
- **Molecular weight** : Approx 10,000 – 15,00,000
- **Chemical name** : cellulose, 2- hydroxypropyl methyl ether.
- **Description** : It is an odorless, tasteless and white or creamy white fibrous or granular powder.
- **Solubility** : Soluble in cold water, forming a viscous colloidal solution, in soluble in chloroform, ethanol.
- **Film forming capacity** : It has film forming ability in 2- 20% w/w concentrations.
- **Moisture content** : It absorbs moisture from the air. The amount of moisture

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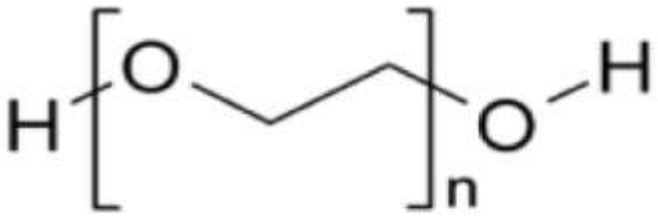
absorption depends on initial moisture content, temperature

- **Category** : Coating agent, film former, stabilizing agent, suspending agent, tablet binder, viscosity- increasing agent.
- **Stability and storage condition :** very stable in dry condition, solution are stable at pH 3.0-11.0. Aqueous solution are liable to be affected by Microorganisms.
- **Safety and regulatory status** : GRAS listed and included in FDA Inactive Ingredient Guide. Human and animal feeding studies have shown HPMC to be safe.

. Polyethelyene glycol

Structure:



- **Synonyms** : Carbowax, Carbowax sentry, Lipoxol, Lutrol E, Macrogola, PEG.
- **Chemical name** : a-Hydro –o-hydroxypoly (oxy-1,2-ethanediyl)
- **Density** : 1.11-1.14 g/cm^3 at 25^{0}C for liquid PEGs: 1.15-1.21 g/cm^3 at 25^{0}C for Solid PEGs.
- **Flash point** : 2388^0 C for PEG 400.
- **Viscosity** : 105-130 cP.
- **Solubility** : All grades of polyethylene glycol are soluble in water and miscible in all Proportions with other polyethylene glycols (after melting, if necessary). Aqueous solution of higher-molecular weight grades may form gels. Liquid polyethylene glycols are soluble in acetone, alcohols, benzene, glycerin, and glycols. Solid polyethylene glycols are soluble in acetone, ethanol (95%), and

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methanol; they are slightly soluble in aliphatic hydrocarbons and

ether, but insoluble in fats, fixed oils, and mineral oil.

- **Functional category :** Ointment base, Plasticizer, solvent, suppository base, tablet and capsule Lubricant.

PHARMACEUTICAL PRODUCTION

1.1.2 AVAILABLE PRODUCTS IN MARKET

Figure 1.4.1 Akarkara powder for health benefitd

1) Akarkara powder /pellitory
   Brand name:- Nutrixia food
   Used for:-vajeekarana(Aphrodisiac)

2) Biotic akarkara powder
   Brand name:- Biotic naturals product
   Used for:- aphrodisiacs ,libido increases,brain booster

3) Akarkara powder
   Brand name ;-planet Ayurveda
   Used for:- libido,sexual health related problems..

4) Akarkara root powder
   Brand name:-bixa botanical
   Used for:-
   Supports healthy nervine function
   Supports oral salivary and dental heal

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CHAPTOR 02 : LITERATURE REVIEW

SR.NO.	SCIENTIST NAME	WORK DONE
1	(Ifra Abdul Quaiyyum 2022)	Concluded that patient had the complaints of difficulty in speech and swallowing at base line which improve after 8 days of treatment at first follow up
2	(Devasankariah et al., 1992)	Demonstrated that aqueous and alcoholic extracts (2%) from the roots of A. pyrethrum show longer local anaesthetics activity than xylocaine in frogs, guinea pigs, and rabbits
3	Mokhtari et al.	Investigated that plant can get rid of a variety of insects, including pink beetles, Indian mealworms, whiteflies, candles, thrips, aphids, Mediterranean flour mites, leafhoppers, ants (apart from fire ants), aphids, crickets, cocoon worms, cabbage worms, and mealy-bugs.
4	Sharma et al. (2010) –	Sharma et al. (2010) –Testosterone: In rats supplemented with A. pyrethrum ethanolic root extract (50–150 mg/kg) for 28 days, Sharma et al. (2010) found dose-dependent increases in testosterone and luteinizing hormone to about two times baseline levels
5	Sharma et al. (2012)–	Testicles: According to research by Sharma et al. (2012), oral administration of 50–150 mg/kg of an ethanolic root extract of Anacyclus pyrethrum to male rats over the course of 28 days appears to increase the weight of the testicles (2.6–12.3%), particularly the epididymis (8.–26.1%) and seminal vesicles (4.3–9.8%).
6	Winter et al.	Discovered that a number of disorders manifest as inflammation. Various A. pyrethrum extracts have been shown in studies to have an anti-inflammatory effect in a rat model of inflammatory edema.

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CHAPTOR 03: RATIONAL,OBJECTIVES AND PLAN OF WORK

- **RATIONAL:-**

To develop oral drug delivery system in the form of fast dissolving film which overcome first pass metabolism and the drug achieve to specific site for greater therapeutic action

- **OBJECTIVES:-**

1. To help in strengthening muscle of toungue
2. For rapid onset of action
3. Easy to use
4. To provide better bioavailability of the drug

- **PLAN OF WORK**

1. Literature survey
2. Selection of API and excipients
3. Collection of marketed root powder
4. Pre formulation study
    a. API characterisation
    b. Organoleptic propertie
    c. Solubility
    d. Identification of phytoconstituent
5. Selection of suitable excipient
6. Design Formulation of film
7. Evaluation of film
8. Result and discussion
9. Conclusion

CHAPTER 04:METHODOLOGY

MANUFACTURING OF MDF

1.SOLVENT CASTING METHOD

- ❑ An aqueous solution of the polymers is prepared in distilled water.
- ❑ Then drug is added to the aqueous polymeric solution .
- ❑ And allowed to stir for 4 hrs and is kept for 1 hr to remove air bubbles
- ❑ Then followed by addition of plasticizers, sweeteners and flavour.
- ❑ Then again stired for 1hr
- ❑ Then the solution is casted onto a petri plate and dried in oven at for 24 hrs
- ❑ Cutting the final dosage form to contain the desired amount of drug,
- ❑ Packaging.

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PREFORMULATION STUDIES

Preformulation testing is the first step in rational development of dosage forms of a drug substance. Preformulation study is the process of optimizing the delivery of drug through determination of physicochemical properties of the new compound that could affect drug performance and development of an efficacious, stable and safe dosage form. It gives the information needed to define the nature of the drug substance and provide a framework for the drug combination with pharmaceutical excipients in the dosage form[45]. Hence, Preformulation studies were performed for the obtained sample of drug for identification and compatibility studies

ORGANOLEPTIC PROPERTIES

Organoleptic properties	Observation
Taste	Pungent
Odour	Aromatic

SOLUBILITY

More soluble in Ethanol than Water

TAXONOMICAL CLASSIFICATION

- Kingdom :- Plantae
- Family :- Asteraceae
- Genus :- Anacyclus

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Preliminary test for phytochemicals

Test for Alkaloids

Mayers test :- 2-3 ml filterate +few drops of mayers reagent	**Positive (Gives ppt)**
Hagers test:- 2-3 ml filterate with hagers reagent	Positive (Yellow ppt)
Wagners reagent :- 2-3 ml filterate + few drops of wagners reagent	Positive (Reddish brown)

Test for flavonoids

Shinoda test :- Dry powder +5ml 95% ethanol few drops conc hcl +0.5gm magnesium turnings	**Positive(Purple colour)**
Sulphuric acid test :- Flavonol +Sulphuric acid	**Positive(Deep yellow colour)**

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We prepare hydroalcoholic extract from root powder by maceration method

↓

50gm powder in 250 ml suitable solvent

↓

50gm powder + 100ml ethanol+150ml dist water = Kept for 3 days

↓

This extract is filtered and evaporated excess water and ethanol at low temperature by using hot plate

↓

We got solid fine powder

Formulation

NAME OF THE INGREDIENT	Role of ingredient
Extract	Therapeutic agent
PEG	Plasticizer
HPMC	Film former
Crosspovidone	Superdisintegrant
Dextrose	Sweetening agent

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FORMULATION OF MOUTH DISSOLVING FILM BY USING ANACYCLUS PYRETHRUM EXTRACT

Batch code	Drug (mg)	PEG400 (mg)	HPMCE15 (mg)	Crosspovidone (mg)	Dextrose (mg)	Citric acid (mg)
B1	50Mg	110	150	1	7	1
B2	50Mg	110	275	1	7	1
B3	50Mg	110	400	1	7	1
B4	50Mg	155	150	1	7	1
B5	50Mg	155	275	1	7	1

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CHAPTOR 05:RESULT AND DISCUSSION

BATCH	DISINTEGRATION	PH	THICKNESS	FOLDING ENDURANCE
B1	27 SEC	7	0.1mm	153
B2	30 SEC	7	0.1mm	156
B3	24 SEC	6	0.1mm	149
B4	27 SEC	5	0.1mm	155
B5	31SEC	7	0.1mm	153

Disintegration test:films placed at the bottom of the disintegration basket tube which is positioned in a 1 L beaker containing phosphate buffer at 37+- 2 degree Celsius and moved the basket assembly up and down with frequency of about 30 cycles per minute. The endpoint when the film was disintegrated into fine particles was determined by a visual inspection

Thickness:measured by using digital vernier calliper.

Folding endurance: Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks . The number of times the film is folded without breaking is computed as the folding endurance value.

Surface PH : The film to be tested was placed in a prtridish and was moistened with 1 ml of distilled water and kept for 1hr . The pH was noted after bringing the electrode of the ph meter in contact with the surface of the formulation and kept for 1 min to allow equilibrium condition.

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CHAPTOR06 : Conclusion and summary

- Mouth dissolving film are innovative dosage form to improve drug delivery,onset of action as because of spit which is there in mouth and better patient compliance.
- Over the past decades fast dissolving films have gained much attention as alternative to conventional dosage form because of numerous advantages like administration without water,accuracy of dosage, portability alternative to liquid dosage form.
- Principal of fast dissolving drug delivery system is to deliver drug across buccal muccosa to achieve systemic effect within short duration of time.
- Films when placed in mouth get dissolved rapidly due to salivary fluid it then releases medicaments and ,get absorbed within blood provide better bioavailability of drug ,quick onset of action, better patient compliance

FUTURE SCOPE

1. Root extract of Anacyclus pyrethrum used for memory enhancing activity in Alzhiemers disease.
2. Anacyclus pyrethrum extract also used for slurred speech in toungue paralysis .
3. Anacuclus pyrethrum plant extract formulation can be prepared for many disease.

CHAPTER NO.05: REFERENCE

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