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Research Article

Formulation and Evaluation of Herbal Gel Containing *Terminalia chebula Retz.*, Leaves Extract

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Abstract: In this context a technique was employed for the formulation of herbal gel by using *Terminalia chebula* Retz.,. The plant is commonly referred as 'King of Medicine' in Tibet, which is widely grown at places up to a height of about 2000 m from the sea level, and in areas with an annual rainfall 100-150 cm and temperature 0-17° C in tropical and subtropical regions of East Asia. It mainly contains active constituents like steroids, flavonoids, tannins, reducing sugar, belleric acid, bellericoside, chebulinic acid, gallic acid, ethyl gallate,punicalagin, terflavin A, terchebin, luteolin, and tannic acid . It is mainly used as antibacterial and antifungal, analgesic, anti-inflammatoy, sun burns and wound healing. Various formulations were prepared with different concentrations of the plant extract and it was evaluated for physical parameters, viscosity, Skin Irritation and Spreadibility. Out of the three formulations the 5% was found to be better in all aspects. Thus it can be used as an alternative for the treatments and drug delivery systems.
Keywords: *Terminalia chebula* Retz., aqueous extract, Carbapol 940, herbal Gel, skin irritation.

INTRODUCTION

India has rich tradition of plant based knowledge of healthcare. The use of the plant based medication is gradually becoming popular throughout the world[1]. The traditional Indian systems of Ayurveda and Siddha medicines support the importance of medicinal plants to treat diseases [2]. The Director of WHO Traditional Medicine reported in 1993 that 80% of the world population rely chiefly on traditional medicine, mainly plant based, specially for their primary health care needs[3]. In India 70% of populations are reported using traditional medicine for primary health care[4]. The present annual turnover of herbal medicinal products manufactured by large companies is estimated to be approximately US $ 300 million, compared to a turnover of approximately US $ 2.5 billion for modern drugs[5].

Terminalia chebula Retz., belongs to family Combretaceae (syn. avyathy) is a dmedium- to large-sized tree distributed throughout tropical and subtropical Asia, including China and Tibet. This tree is found in the forests of northern India, Uttar Pradesh and Bengal, and is common in Tamil Nadu, Karnataka and southern Maharastra. *Terminalia chebula* is commonly known as black myroblans in English and harad in Hindi[6]. The *Terminalia* consists of 250 species and widely distributed in tropical areas of the world. The fruit of *Terminalia chebula* is consider as the "king of medicines" by Tibetans and second-to- none by ayurvedic apothecaries, and also held in high regard by other folk medicinal practitioners[7]. In different parts of India, the plant is known by different vernacular names /local names are Telugu- Karakkaya, Nalla karaka ,Tamil - Kadakkai,English - Black myrobalan, Hindi - Chhoti har[8]. As per the ethnomedicinal information the various parts of *Terminalia chebula Retz.*, possess medicinal properties. The fresh leaves infusion are used to cure bacterial infection, fungal infection and as vermifuge/ pediculicide[9].Dried whole plant are used for Fevers, cough, asthma, urinary diseases, piles, worms, rheumatism and scorpions tingand liver[10]. Roots are used for astringent, purgative, stomachic, laxative healing of wounds and scalds. Fruits are used for Antibacterial and antifungal spectrum and also inhibits growth of E.coli, Bark are used for including heart disease and related chest pain, high blood pressure, and high cholesterol and to increase sexual desire[11]. The reported chemical constituents present in *Terminalia chebula Retz.*, are Fruits: triterpenes arjunglucoside I, arjungenin, and the chebulosides I and II. Other constituents include a coumarin conjugated with gallic acids called chebulin, as well as other phenolic compounds including ellagic acid, Leaves contains 35% tannins Roots contains oleanane triterpenoids arjunic acid, arjungenin,

glycosides, and cardenolide Bark contains Luteic acid ,Stem bark contains arjungenin and its glucoside, belleric acid, bellericosideFlowers contains Flowers contain chebulin, a glycoside[12].

Among the skin care formulations, single-phase gel is extensively used for cosmetic products due to its aesthetic appearance[13] .Moreover, organic macromolecules are uniformly distributed throughout a liquid in such a manner that no apparent boundaries exist between the dispersed macromolecules and the liquid[14]. *Terminalia chebula Retz.*, plants are found to possess antinflammatory activity, wound healing, Antibacterial and antifungal Keeping this in view, we planned to bring it our as semisolid external preparation (*Terminalia chebula* Retz., extract) and to screen its efficacy for topical anti – inflammatory, wound healing, Antibacterial and antifungal activity by gel formulation. Moreover literature survey revealed that there is no scientific validation for this formulaion and stability studies . So, an attempt was made to formulate the gel of aqueous extract of the leaves of *Terminalia chebula Retz.*, and their stability studies.

MATERIALS AND METHODS

Plant Materials

Collection, identification and authentication of raw *Terminalia chebula Retz.*, was done. Fresh leaves of *Terminalia chebula Retz.*, were collected in a street in Eluru, west godavari district, Andhra pradesh, India. In july and authenticated by department of botony, Acharya Nagarjuna university, guntur, India. A herbarium is maintained in sir crr College of Pharmacy, Eluru, Andhra Pradesh , India.

Chemicals

Carbopol 940 (Merck Ltd), Methyl Paraban (Sigma Aldrich Cmemicals), Propyl Paraben (WIN Medicare Pvt. Ltd), Propylene glycol-400 (SD Fine Chemical Ltd), Triethanolamine (SD Fine chemical Ltd).

Animals

Albino rats of either sex weighing between 200-250 g procured from swetha enterprises, were used for the present investigation. Animal Ethical Committee approved experimental protocol under guidelines of CPCSEA, New Delhi. The rats were housed at controlled temperature (25±2ºC) and 12hrs dark-light cycle and provided basal diet in the form of pellets, water ad libitum

Preparation of Topical Gel

Different combinations of *Terminalia chebula Retz.*, leaves aqueous extract (1% & 5%) were tried with different types of polymers (Carbopol 940) using various formulae[15]. The following few combination with Carbopol 940 resulted in the best gel formulation, which was smooth and stable. Control sample also was prepared for testing of animal to check the activity of control ingredients.

Method for Preparation of Gel Containing Extract

1 g of Carbopol 940 was dispersed in 50 ml of distilled water kept the beaker aside to swell the carbopol 940 for half an hour and then stirring should be done to mix the carbopol 940 to form gel. Take 5 ml of distilled water and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath. Solution was cooled and Propylene glycol 400 was added. Further required quantity of *Terminalia chebula Retz.*, leaves extract was mixed to the above mixture and volume made up to 100 ml by adding remaining distilled water. Finally full mixed ingredients were mixed properly to the Carbopol 940 gel with continuous stirring and triethanolamine was added drop wise to the formulation for adjustment of required skin pH (6.8-7) and to obtain the gel at required consistency. The same method was followed for preparation of control sample without adding any *Terminalia chebula Retz.*, leaves extract.

Formulation

As per method described above the formulae were tabulated in Table 1. Along with control sample gel were prepared with addition of 1g and 5g of *Terminalia chebula Retz.*, leaves extract to prepared 1% and 5% *Terminalia chebula Retz.*, gel respectively.

EVALUATION OF TOPICAL GEL FORMULATION

Physical Evaluation

Physical parameters such as color and appearance were checked.

Measurement of pH

The pH of various gel formulations were determined by using digital pH meter. 2.5gm of gel was accurately weighed and dispersed in 25ml of distilled water and stored for two hours .The measurement of pH of each formulation was done.

Spreadibility[17]

Spreadibility was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end[16]. By this method spreadibility was measured on the basis of slip and drag characteristics of gels. An excess of gel (about 2g) under study was placed on this ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A. one kg weighted was placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of the gel between the slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 gm. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval

Indicate better spreadibility. Spreadibility was calculated using the following formula:

S = M × L / T

Where,

S = Spreadibility,

M= Weight in the pan (tied to the upper slide)

L = Length moved by the glass slide

T = Time (in sec.) taken to separate the slide completely each other.

Stability Study

The stability study was performed as per ICH guidelines 6. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz. 250 C ± 20C/ 60% ± 5% RH, 300 C ± 20C/ 65% ± 5% RH, 400 C ± 20C/ 75% ± 5% RH for a period of three months and studied for appearance, pH, and spreadibility.

Extrudabilty[18]

The gel formulation were filled in standard capped collapsible aluminium tubes and sealed by crimping to the end. The weight of tubes were recorded and the tubes were placed between two glass slides and were clamped. 500gm was placed over the slides and then the cap was removed. The amount of extruded gel was collected and weighed. The percent of extruded gel was calculated as

1. When it is greater than 90% then extrudability is excellent.
2. When it is greater than 80% then extrudability is good.
3. When it is 70% then extrudability is fair.

Viscosity[19]

Viscosities of gels were determined using Brookfield viscometer. Gels were tested for their rheological characteristics at 25^{o}C using Brookfield viscometer (DV-III programmable Rheometer). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30seconds between 2 successive speeds and then in a descending orders.

APPLICATION OF HERBAL GEL AND SKIN IRRITATION STUDY

0.5 gm of the herbal gel was used as the test substance was applied to an area of approximately 6 cm2 of skin and covered with a gauze patch. The patch was loosely held in contact with the skin by means of a semi-occlusive dressing for the duration of 1 hour and gauze was removed. At the end of the exposure period, i.e., 1 hour, residual test substance was removed, without altering the existing response or integrity of the epidermis. Observations have recorded after removal of the patch. Control animals were prepared in the same manner and 0.5 gm of the gel base i.e., gel formulated using all ingredients except the herbal mixture was applied to the control animals and observations were made as similar to the test animals[20].

The gel was applied to the skin once a day for 7 days and observed for any sensivity and the reaction if any was graded[21].

RESULTS AND DISCUSSIONS

The herbal gel was prepared and subjected to evaluation of the various parameters. The herbal Gel was light brown in color and translucent in appearance and had a cool and smooth feeling on application. pH also maintained constant throughout the study which was found to be 6.9 to 7.0 and the gel was non-irritant upon application on the skin. Spreadibility were also measured and found to be less variant than the initially prepared gel after performing stability study. Further stability test for three months has been carried out and results revealed gel containing 5% *Terminalia chebula Retz.*, leaves showed better stability than 1%. The gel was non-irritant upon application on to the skin. The control and experimental rats showed no signs of tremor, convulsion and reflex abnormalities.

Table-1: Control and *Terminalia chebula Retz.*, leaves aqueous extract formulation prepared with this ingredients along with quantity

S.N0	INGREDIENTS	Control	F_1	F_2
1.	carbopol 940	1 gm	1 gm	1 gm
2.	Methyl Paraben (0.5%)	0.4 ml	0.2 ml	0.2 ml
3.	Propylene glycol 400 (5%)	5 ml	5 ml	5 ml
4.	Triethanolamine (q.s)	1.2ml	1.2ml	1.2ml
5.	Distilled water	Upto 100 ml	Upto 100ml	Upto 100ml
6.	T.C Extract (1%)	_	1g	_
7.	T.C Extract (5%)	_	_	5g

T.C=*Terminalia chebula* Retz.,

Physical evaluation of all formulations

Table: 2 Stability of developed gels at Initial month at 35^{0}C

Formulation	Colour	Appearance	pH	Spreadibility (GM.CM/SEC)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.99 ±0.06	14.77±1.32	Excellent	1640±40
F_1 -1% T.C Extract	Pale brown	Clear and Transparent	6.35±0.03	14.28±0.86	Excellent	1627±23.09
F_2 -5% T.C Extract	Pale brown	Clear and Transparent	6.56±0.08	10.62±1.16	Fair	1613±22.09

Table-3: Stability of developed gels at second month at 30^{0}C

Formulation	Colour	Appearance	pH	SpreadibilitY (GM.CM/SEC)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.95 ±0.07	14.29±1.32	Excellent	1638±30
F_1 -1% T.C Extract	Pale brown	Clear and Transparent	6.60±0.06	13.28±0.86	Excellent	1627±23.09
F_2 -5% T.C Extract	Pale brown	Clear and Transparent	5.34±0.06	10.62±1.16	Fair	1613±22.09

Table-4: Stability of developed gels at third month at 28^{0}C

Formulation	Colour	Appearance	pH	Spreadibility (GM.CM/SEC)	Extrudability	Viscosity (Cps)
Control	White	Clear and Transparent	6.99 ±0.06	14.39±1.32	Excellent	1640±40
F_1 -1% T.C Extract	Pale brown	Clear and Transparent	6.6±0.06	13.35±0.86	Excellent	1627±23. 09
F_2 -5% T.C Extract	Pale brown	Clear and Transparent	6.6±0.06	10.42±1.16	Fair	1680±40

Table 5: Skin Irritation Study Results.

Treatment	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Control	A	A	A	A	A	A	A
F_1 -(1%)	A	A	A	A	A	A	A
F_2 -(5%)	A	A	A	A	A	A	A

A – No reaction, B – Slight patchy erythema, C –Slight but confluent or moderate but patchy erythema, D – Moderate erythema, E – Severe erythema with or without edema.

CONCLUSION

The plant *Terminalia chebula* Retz., was selected for the study, whose extract was very useful in the treatment of wounds. Literature survey revealed that this plant is used traditionally for various ailments, especially for its wound healing property. Extensive scientific studies were not performed on this plant. It is an attempt made to establish the herbal gel containing *Terminalia chebula* Retz., Leaves extract at various concentrations (1% and 5%). The studies revealed that the developed single herbal formulation consisting 1% *Terminalia chebula* Retz., leaves extract comparatively better than later other formulation but all the formulations were non irritant and did not show any skin toxicity when applied daily for 7 days in rats. Its antibacterial and antifungal property was not under taken for any scientific study with herbal gel. Hence the present work is performed.

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REFERENCE

1. Wohlmuth H, Oliver C, Nathan PJ; A review of the status of Western herbal medicine in Australia. J Herb Pharmacother 2002; 2: 33-46.
2. Beusher N, Bodinet C, Neumann-Haefelin D, Marston A, Hostettmann K; Antiviral activity of African medicinal plants, J. Ethnophar-macol, 1994; 42: 101-109.
3. Akerele O. Nature's Medicinal Bounty: don't throw it away. World Health Forum 1993, 14:390-395.
4. Zhang X; Regulatory Situation of Herbal Medicines A worldwide Review. World Health Organization, 1998; 26.

5. Haq I; Safety of medicinal plants. Pakistan J. Med. Res, 2004; 43(4): 203-210
6. Ammar S, Michael H, Pirkko H, Kalevi P; Inhibition of Cancer Cell Growth by Crude Extract and the Phenolics of *Terminalia chebula* Fruit. J. Ethnopharmacol, 2002; 81: 327-336.
7. Karel DK, Ammar S, Jari S, Marja K, Jyrki L, Peteri T, Kalevi P; The Structural and Conformational analyses and antioxidant activities of Chebulinic acid and its thrice-hydrolyzed derivative,2,4-chebuloyl-ßd- glucopyranoside, isolated from the fruit of *Terminalia chebula* . ARKIVOC, 2004; 7: 83-105
8. wikipedia.org/wiki/Eclipta_prostrata
9. Holdsworth DK; A Phytochemical Survey of Medicinal Plants of the D'entrecasteaux Islands. Sci New Guinea, 1974; 2: 164-171.
10. Hehmann A, Kaya K; Watanabe MM Selective control of Microcystis sp using an amino acid a laboratory assay. J Appl Phycol, 2002; 14: 85-9.
11. Abailable from http://www.indiamart.com/neerajtraders/ayurvedic-herbal-products.html
12. Bhatt VJ; Calcutta: Siddheshwar press; Rajanighantu by Narahari; 1933; 287–8.
13. Guterres SS, Alves MP, Pohlamnn AR; Polymeric nanoparticles, nanospheres and nanocapsules for cutaneous applications. Drug Target Insights, 2007; 2147-157.
14. Allen LV Jr; The Basics of Compounding. Int J Pharm Compd. 1999; 3: 385-389.
15. Manosroi A, Jantrawut P, Akihisa T, Manosroi W, Manosroi J; In vitro and in vivo skin anti-aging evaluation of gel containing niosomes loaded with a semi-purified fraction containing gallic acid from *Terminalia chebula* galls. Pharmaceutical biology, 2011; 49(11):1190-1203.
16. Carl AB, Edward RA; Text book of clinical chemistry and molecular diagnostics.4th rev. ed. W.B Saunders Philadelphia, 2001.
17. Patel RP, Kamani R; Formulation optimization and evaluation of mometazone furoatecream. J Pharm Res., 2002; 2: 1565-1569.
18. Panigrahi L, Ghosal SK, Pattnaik S, Maharana L, Barik BB; Effect of permeation enhancers on the Release and permeation kinetics of Lincomycin Hydrochloride gel formulations through Mouse skin. Indian J Pharm Sci., 2006; 205-211
19. Pandit JK, Bharathi D, Srinatha A, Ridhurkar DN, Singh S; Long acting ophthalmic formulation of indomethacin: Evaluation of alginate gel systems. Ind J Pharm Sci., 2007; 69: 37-40.
20. Das K, Dang R, Machale UM, Fatepuri S; Formulation and evaluation of herbal gel containing stevia leaves extract. The Pharma Review, 2010; 8(44):112-118.
21. Prakash PR, Rao NR, Chowdary S; Formulation, evaluation and anti-inflammatory activity of topical etoricoxib gel. Asian J. of Pharm. and Clinical Res, 2010; 3:126.