Novel Approaches in Drug Designing & Development
ISSN: 2575-8942

Juniper Publishers
key to the Researchers

Research Article
Volume 6 Issue 5 - April 2023
DOI: 10.19080/NAPDD.2023.06.555692

Nov Appro Drug Des Dev

Formulation and Pharmaceutical Analysis of Unani Anti-Inflammatory and Analgesic Gel

Yumna Baqi, Qazi Zaid Ahmad* and Huda Nafees

Department of Saidla, Faculty of Unani Medicine, Aligarh Muslim University, Aligarh, India

Submission: November 11, 2022; **Published:** April 21, 2023

***Corresponding author:** Qazi Zaid Ahmad, Department of Saidla, Faculty of Unani Medicine, Aligarh Muslim University, Aligarh, India

Abstract

Background and objective: *Qairooti* (Cerate or Cera Beeswax Salve) a topical dosage form in Unani System of Medicine which are commonly being used for different indications such as pain, inflammation, respiratory infection, wound, and injury. These formulations are quite safe and effective in such ailing conditions attributed to its active constituents of their ingredients which have analgesic, anti-inflammatory and soothing activity. In view of above the present study has undertaken to redesign the *Qairooti Aarad-e karsana,* a traditional Unani dosage form into advance gel in order to provide the better compliance of the patients and upgrade this formulation up to the global standard.

Material and Method: *Qairooti Aarad-e karsana* was converted in to gel by the method of [1]. All the ingredients were extracted with the soxhelt's apparatus and admixed with the excipients enlisted in (Table 1). The different batches were prepared. The most suitable batch was selected for pharmaceutical analysis and reproducibility.

Result: The final product was inconsonance with physicochemical parameters and pharmaceutical guideline. Moreover, its aesthetic appearance and efficacy also significantly increased as demonstrated in preliminary study along with better compliance to the patient.

Introduction

Nowadays, the worldwide growing resurgence towards the traditional medicine and natural products like never before. This is matter of fact that the classical formulations and dosage forms are time tested but their quality, pharmacodynamics and pharmacokinetic activities should be evidence based. Henceforth, it is utmost important to standardize the single drugs with modern parameters and transform the classical dosage form in to advance dosage form. Recently a lot of research work has been carried out which consist of isolation of active constituents of herbs to evaluate their efficacy and activity acclaimed by physician of traditional medicines along with standardization and quality assurance with sophisticated instrument such as HPLC, Spectroscopy etc.

Further, the biological activity of the plants has been also studied in vivo and in vitro to make the traditional medicine evidence based and to understand their mechanism of action in scientific manner on modern parameters. Some selected plants have also synthesized to the nanoparticle to provide better efficacy and better compliance to the patient.

Unani System of Medicine (Greek Medicine) is one of the most cherished traditional medicines in this subcontinent as the system is practiced since centuries not only quite safe and effective but most compatible to the biological system taking in account the human temperament, naturally processed drugs used so appropriately with inconsonance of pathology, temperament of organ along with selection criteria of drug according to severity of disease. Unani System of Medicine has rich heritage of classical pharmacopoeial dosage form which are commonly being used by Unani physician to combat the different pathological conditions and chronic disorders successfully by eradicating the root cause of the disease in terms of removal of causative factor and restoration of physiology with core emphasis on natural way with least compromise on adverse effect [2].

One such most useful classical dosage form *Qairooti* (Cerate) a medicinal salve or ointment has a base of wax and oil based. Beeswax has unique characteristics to builds stable emulsions and increases water absorbance of creams and ointments [3]. There are many types of *Qairooti* in Unani Pharmacopoeia recommended for different indications such as pain, inflammation, wound and injuries.

Although the topical formulations are quite effective in alleviating pain and inflammation but in present scenario it is lacking the criteria of advance dosage form, better compliance of the patients and aesthetic commercial requirement.

In view of above, taking into account of several advantages associated with *Qairooti Aarad-e karsana,* it was developed into advance gel form to enhance its efficacy and to make it at par with recent advance dosage form, provide better patient compliance and global acceptance. The pre and post formulation study along with development of standard operative procedure for the further reference, reproducibility and quality assurance were also carried out.

Material and Methods

The study was undertaken to redesign and development of *Qairooti Aarad-e- karsana* into the gel form [4]. This formulation is used as an anti-inflammatory and analgesic. The study was carried out in two phases. In phase 1 the preparation of the formulation was done and in phase 2 evaluation of the prepared gel was carried out. The ingredients of *Qairooti Arad-e-Karsana* are given in the following (Table 2).

Procurement of Drugs: The ingredients of formulation were procured from the Dawakhana Tibbiya college, AMU, Aligarh. Ingredients were identified and authenticated by Botanist, Prof. Wazahat Hussain, Department of Botany A.M.U, Aligarh. The voucher specimen No. 39/05, has been deposited in the museum of department of Saidla, A.M.U.

Chemicals and reagents: All the chemical and reagents used for the study were of analytical reagents grade.

Preparation of the extract

All the ingredients of *Qairooti Arad-e-Karsana* listed in Table 2 were cleaned to remove the impurities present in them and are allowed to dry in the oven at 40 °C. After drying, they are converted into coarse powder form by using grinder. Then extraction is done by using Soxhlet apparatus in hydro alcoholic solvent for 6 hours. Then the extract was dried at water bath at controlled temperature and stored for further use [1].

Excipients used in the formulation of the gel

Carbopol 940 and Sodium CMC, Propyl Paraben, Methyl Paraben, Propylene glycol, Triethanolamine. All the chemicals were of standard grade. The quantity and purpose for the use of excipients in making the gel depicted in Table 1 [1].

Table 1: Excipients used for the preparation of the Gel.

S.No	Name of the Excipient	Quantity	Action
1	Carbopol 940	0.5gm	Increase Viscosity
2	Propylene glycol	5ml	Absorbs water
3	Methyl paraben	0.03gm	Preservatives
4	Propyl paraben	0.01gm	Preservatives
5	Triethanolamine	As required	pH balancer
6	Methylene blue	0.5gm	Colouring agent
7	Camphor and Mentha oil	0.2gm	Aromatic agent

Table 2: Ingredients of Qairooti Arad-e-Karsana mentioned in NFUM Part 1.

S.No	Unani Name	Scientific Name	Part Used	Quantity
1	Aarad-e-karsana	Pisum sativum	Seeds	150g
2	Tukhm-e-hulba	Trigonella foenum	Seeds	150g
3	Kalonji	Nigella sativa	Seeds	60g
4	Asl-ul-soos	Glycyrrhiza glabra	Root	60g
5	Aqarqarha	Anacyclus pyrethrum	Root	50g
6	Mom zard	Beeswax	Wax	100g
7	Roghan-e-gul	Rosa damascena	Petals	800g

Method of preparation of the gel

For the preparation of the gel, 0.5gm Carbopol 940 (water soluble polymer, used to prepare medium to high viscosity gels) was taken in 50ml distilled water and dissolved in it. The gel is prepared by using polymer base like Sodium CMC (used as emulsifier and as a thickening agent). 0.5 gm of Sodium CMC was added to it, after placing it on heating stirrer. 0.01 gm Propyl paraben and 0.03 gm of Methyl paraben (preservatives) was added in 5ml of distilled water and was dissolved by heating on water bath for 1 min. 5ml of propylene glycol was added after cooling it, which helps in absorption of water. Then 1gm of extract was dissolved in 100ml of distilled water. 1ml of Triethanolamine (pH balancer) was added to it drop wise to obtain the required consistency. Finally, full mixed ingredients are mixed properly to the base with continuous stirring. [1,5-9].

How to cite this article: Yumna Baqi, Qazi Zaid Ahmad and Huda Nafees. Yadav. Formulation and Pharmaceutical Analysis of Unani Anti-Inflammatory and Analgesic Gel. Nov Appro Drug Des Dev. 2023; 6(5): 555692. DOI: 10.19080/NAPDD.2023.06.555692

Evaluation of the gel-Organoleptic characteristics-

I. Appearance – the gel was tested visually for appearance to identity the presence of any aggregates.

II. Colour – colour of the gel was observed visually.

III. Odor- odor was observed by smelling the gel directly.

IV. Consistency – consistency was checked visually.

V. Homogeneity –the gel was tested for homogeneity by visual inspection after the gel has been set in the container. They were tested for their appearance and presence of any aggregates.

VI. Stickiness – stickiness was also checked by spreading on skin surface.

VII. Grittiness – gel was checked for grittiness by spreading on the skin surface.

VIII. Phase separation – gel was observed visually for phase separation.

Determination of pH

pH of 1% and 10% of the gel was determined by using digital pH meter [1].

Spreadability

It is the term used to donate the extent of the area to which gel readily spreads on application to the skin or the affected part of the skin. The therapeutic efficacy of the formulation also depends on its spreading value. For measuring the spreadabilty two glass slides of standard dimension were taken. The herbal gel formulation was placed over one of the slides. The other slide was placed on the top of the gel, such that the gel was sandwiched between the two slides. 1gm weight the gel was placed on the upper slides so that the gel was between the two slides was pressed uniformly to form a thin layer. The weight was removed and the excess of gel adhering to the slides was scrapped off. A 60-gm weight was tied to the upper slide carefully. The time in seconds required to separate the two slides was taken as a measure of spreadabilty.

Spreadabilty was calculated by using the following formula:

$S = mx\ l/t$

Where, spreadabilty is the weight tied to upper slides, l is the length of the glass slides, t is the tie taken in seconds [10,11].

Density

The density is physical property of matter. For a homogeneous object it is defined as the ratio of its mass (m) to its volume (V) [12].

$density = m/v\ [kg\ m^3]$

Viscosity

Viscosity is the measure of the internal friction of a fluid. This friction becomes apparent when a layer of fluid is made to move in relation to another layer. The fundamental unit of viscosity measurement is the "poise." The Digital viscometer rotates a disc or cylinder in a fluid sample and measures the torque needed to overcome the viscous resistance to the induced movement. This is done by rotating the spindle with an electric motor [12,13].

Result

In the present study, different batches of gel were prepared as preliminary batches and final study batches. The final batch was thoroughly observed for any change in physical properties. The results for the organoleptic characters were found to be as follows:

The gel was translucent and clear in appearance having camphoric odour and semiliquid in consistency. the colour of the gel was light or pale yellow., homogenous in nature. Also, the gel was non- sticky, checked by spreading on skin surface. The Grittiness of the gel was checked by spreading on the skin surface results showed that it was non-gritty, and the results of the phase separation showed that there was no phase separation.

Physicochemical parameters

pH of the Gel: The pH of all topically applied formulations must show compatibility with pH of skin. The average pH of all the four samples of emulgel were within range of pH of human skin, i.e., 5.5 to 6.0. It was observed that the mean value freshly prepared gel in 1% and 10% Solution was found to be 7.2 ± 0.520 and 7.5± 0.53.

Spreadabilty- Spreadability is the extent to which an emulgel spread when applied to skin or target part and is the main feature of formulation upon which therapeutic efficacy depends. [14] It has been observed that at low temperature, the value of spreadability coefficient of gel decreased because the viscosity of the emulgel decreased. The mean value of spreadability was found to be 12.75 ± 0.89 gm.cm/sec.

Viscosity – An important parameter that might have influenced drug release was the viscosity of formulations. In general, the higher viscosity of topical formulation, the lower drug release rate (10,13). Viscosity seems to influence drug release from different pharmaceutical forms. Gel formulation, which presented the lowest viscosity, showed the highest drug release rate, [15,16]. Viscosity of gel was determined using Digital viscometer at 28 °C with a spindle speed of the viscometer rotated at 30 rpm. The viscosity of the gel was found to be $4.1x\ 10^3$ centipoise, with torque of 10.2 % which was very low and suggests the higher release rate of the drug.

Density-of the gel

The density of the gel was found to be 1.092± 0.43 g/ml.

Discussion

Herbal medicine is gradually becoming popular throughout the world. Nowadays pupils are preferring natural systemic and topical formulation to restore the physiological function due

How to cite this article: Yumna Baqi, Qazi Zaid Ahmad and Huda Nafees. Formulation and Pharmaceutical Analysis of Unani Anti-Inflammatory and Analgesic Gel. Nov Appro Drug Des Dev. 2023; 6(5): 555692. DOI: 10.19080/NAPDD.2023.06.555692

to their safety and efficacy. More than two third of the world population rely on the natural products for their health-related problems as they are well connected these regimens through the culture, tradition and long cherished history of the indigenous system of medicine, viz Ayurveda Unani etc. [17,18].

The unani system of Medicine which is old and time-tested way of treatment and provides total cure of chronic and complicated disorders of the body through eradicating the root cause of disorder by single and compound formulation along with recommended regimen [19]. The system which is well known for its vast treatise of formulary viz Qarabadeen containing most effective dosage forms and formulation which are based on experience and observation of Unani physicians since centuries while they are most effective and relevant to manage the chronic ailments. The major hurdle in use of these formulation or dosage form is that they couldn't upgraded up to the global standard and thereby noncompliance of the patients.

Now its high time to find out the hidden jevels from the unani treatise and remodelling them in to advance dosage form of global standard in accordance with modern guidelines and regulatory bodies for the better compliance, acceptance and commercialization [20]

So, keeping in view of above, the study was undertaken to develop "*Qairooti Aarad-e- karsana*" a potent drug to relieve the chest pain caused by respiratory tract and lung infection. The topical anti-inflammatory drugs are always having an added advantage on oral anti- Inflammatory medicines which causes local mucosal irritations and metabolism in the first pass metabolism, which occurs in the liver and leads to partial inactivation. Topical application of anti-inflammatory agents at the site of inflammation can overcome their systemic side effects and improve their therapeutic activity [21]. Topical drug administration is a locally used drug delivery system anywhere on the body through ophthalmic, rectal, vaginal and skin. Skin is one of the most easily accessible organs of the human body for topical administration and also the main route of topical drug delivery system [22]. For topical treatment of dermatological disease as well as skin care, a wide variety of vehicles ranging from solids to semisolids and liquid preparations is available to clinicians and patients. Within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to promptly achieve and then maintain the desired drug concentrations.

From the results it is evident, the prepared gel from the ingredients of *Qairooti-Aarad-e-Karasana* has been evaluated on different pre formulation, in process and post formulation parameters and the guideline of regulatory body. It has qualified as per with the given criteria or guideline. The product has not only qualified physicochemical parameters, but its aesthetic appearance and efficacy has also significantly increased as demonstrated in preliminary study. In nutshell the product will get acceptance in masses and will provide a safe and effective treatment of local pain and inflammation along with great commercial value.

Conclusion

Qairooti a safe and effective topical dosage form of Unani System of Medicine which is being successfully used to treat local pain, inflammation, and respiratory disorder since centuries. The formulation is quite effective, but its classical form requires renovation and upgradation in accordance with global standard and pharmaceutical regulatory guidelines. So, the redesigned formulation will not only comply to the pharmaceutical guidelines but provide better compliance to the patient. The standard operative procedures (SOPs) may also be used for reproducibility and further reference.

Acknowledgement: The authors gratefully acknowledge the Chairman, Department of Saidla, Ajmal Khan Tibbiya Collge, Faculty of Unani Medicine, A.M.U, Aligarh, UP, India for providing all the financial and technical support for this study.

Conflict of Interest: Authors declare there is no conflict of interest.

References

1. Shadab M, Shamsi S (2020) Original Research Article (Experimental): Design and Development of Unani Emulgel for Vitiligo. J Ayurveda Integr Med 11(3): 199-205.
2. Sen S, Chakraborty R (2017) Revival, modernization, and integration of Indian traditional herbal medicine in clinical practice: Importance, challenges and future. J Tradit complement Med 7(2): 234-244.
3. Mosleh G, Badr P (2016) Qairooti (Cerate or Cera Beeswax Salve) in Traditional Iranian Pharmacy. Iran J Med Sci 41(3 Suppl): S8.
4. Ministry of Health and Family Welfare (1981) National Formulary of Unani Medicine, Part I, New Delhi, India
5. Kaur LP, Garg R, Gupta GD (2010) Development and evaluation of topical gel of minoxidil from different polymer bases in application of alopecia. Int J Pharmacy and Pharm Sci 2(3): 43-47.
6. Bele AA, Jadhav VM (2010) Formulation and evaluation of Herbal Drug. Drug Invention Today 2(7).
7. Gupta A, Mishra AK, Singh AK, Gupta V, Bansal P (2010) Formulation and evaluation of topical gel of diclofenac sodium using different polymers. Drug Invention Today 2(5): 250-253.
8. Shivhare UD, Jain KB, Mathur VB, Bhusari KP, Roy AA (2009) Formulation development and evaluation of diclofenac sodium gel using water soluble polyacrylamide polymer. Digest Journal of Nanomaterials & Biostructures (DJNB) 4(2): 285-290.
9. Das MK, Ahmed AB (2007) Formulation and ex vivo evaluation of rofecoxib gel for topical application. Acta Pol Pharm 64(5) : 461-467.
10. Fatima S, Zaman R, Haider N, Shamsi S, Alam A (2017) Design and development of Unani anti-inflammatory cream. J Ayurveda Integr Med 8(3): 140-144.
11. Bhura MRG, Bhagat KA, Shah SK (2015) Formulation and evaluation of topical nano emulgel of adapalene. World Journal of Pharmaceutical Sciences 1013-1024.

How to cite this article: Yumna Baqi, Qazi Zaid Ahmad and Huda Nafees. Yadav. Formulation and Pharmaceutical Analysis of Unani Anti-Inflammatory and Analgesic Gel. Nov Appro Drug Des Dev. 2023; 6(5): 555692. DOI: 10.19080/NAPDD.2023.06.555692

12. Daniels F, Alberty RA (Eds.) (1966) Physical Chemistry, John Wiley & Sons, New York, USA, pp. 342-346

13. Lira AAM, Sester EA, Carvalho ALM, Strattmann RR, Albuquerque MM, et al. (2008) Development of lapachol topical formulation: anti-inflammatory study of a selected formulation. AAPS PharmSciTech 9(1): 163-168.

14. Anwar E, Ramadon D, Harmita (2014) Formulation and Evaluation of Gel and Emulgel of Chili Extract (Capsicum frutescens L.) As Topical Dosage Forms. International Journal of Pharmacy and Pharmaceutical Sciences 6(suppl 3): 13-16.

15. Abd El-Bary A, Shalaby S, Abd El-Aal S (2001) Formulation and stability of chloramphenicol gel and emulgel. Bull Fac Pharm 39: 89-99.

16. Mohamed MI (2004) Optimization of chlorphenesin emulgel formulation. AAPS J 6(3): e26.

17. Yadav P, Pandiaraj T, Yadav V, Yadav V, Yadav A, et al. (2020) Traditional values of medicinal plants, herbs and their curable benefits. Journal of Pharmacognosy and Phytochemistry 9(1): 2104-2106.

18. Jamadar MJ, Shaikh RH (2017) Preparation and evaluation of herbal gel formulation. Journal of Pharmaceutical Research and Education 1(2): 201-224.

19. Ansari S, Khan QA, Anjum R, Siddiqui A, Sultana K (2017) Fundamentals of Unani system of medicine-a review. European Journal of Biomedical and Pharmaceutical Science 4: 219-223.

20. Hongal S, Torwane NA, Pankaj G, Chandrashekhar BR, Gouraha A (2014) Role of unani system of medicine in management of orofacial diseases: A review. J Clin Diagn Res 8(10): ZE12-ZE15.

21. Muzzalupo R, Tavano L (2015) Niosomal drug delivery for transdermal targeting: recent advances. Research and Reports in Transdermal Drug Delivery 4: 23-33.

22. Parashar B, Kabra A, Chandel A (2013) Formulation and evaluation of gel containing miconazole nitrate an antifungal agent. Int J Pharm Res Rev 2(6): 18-28.

DOI: 10.19080/NAPDD.2023.06.555697

How to cite this article: Yumna Baqi, Qazi Zaid Ahmad and Huda Nafees. Formulation and Pharmaceutical Analysis of Unani Anti-Inflammatory and Analgesic Gel. Nov Appro Drug Des Dev. 2023; 6(5): 555692. DOI: 10.19080/NAPDD.2023.06.555692