Symposium

Standardization of Unani polyherbal formulation, Qurse-e-Hummaz: A comprehensive approach

Abstract

Background: An increase in the awareness about the advantages of the traditional system of medicines has led to the commercialization of the formulations used for the treatments. Manufacture of these medicines to meet this increasing demand has resulted in a decline in their quality, primarily due to a lack of adequate regulations pertaining to this sector of medicine. Hence, it is necessary to come up with a systematic approach to develop well-designed methodologies for the standardization of polyherbal formulations which are used in traditional systems of medicine. **Materials and Methods:** Qurs-e-Hummaz formulations were prepared by a qualified "Hakim" (Unani medical practitioner) of Faculty of Unani Medicine, Hamdard University, as per the formula and instruction given in National Formulary of Unani Medicine. **Results:** Various quality control parameters such as organoleptic evaluations (color, odor, taste, and consistency), physicochemical evaluations (loss on drying, disintegration time, moisture content, total ash, acid insoluble ash, water soluble ash, pH of 1 and 10% solution, extractive values, water soluble matter, alcohol-soluble matter, and total phenolic content) and thin layer chromatography fingerprint profiling have been carried out in triplicate. The evaluation of contaminants such as heavy metals, aflatoxins, pesticide residues, and microbial contamination has also been carried out in the formulation. **Conclusion:** Help in maintaining the quality and batch to batch consistency of many important polyherbal formulations.

Key words:
Polyherbal formulation, qurs-e-Hummaz, standardization

Introduction

The Unani System of Medicine include a large number of traditional formulations and used since a long time in India and abroad. This system consists of different types of formulations like Itrifal, Jawarish, Majun, Qurs, and Habbs and has been ignored for scientific validation of these formulations as well as for the quality control using modern analytical techniques.[1,2] Qurs-e-Hummaz is a tablet formulation mentioned in the National Formulary of Unani Medicines (NFUM), which has been commonly used in Unani as an anti-inflammatory drug. It composed seven ingredients such as *Rumex vesicarius*, *Bambusa bambos* Druce, *Rosa damascena*, *Berberis aristata*, *Coccus lacca*, *Aristolochia rotunda*, and *Crocus sativus*.[3,4]

The aim of the present research work was to develop high standard quality parameters for a polyherbal formulation

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which is frequently used in the Unani system of medicine. Qurs-e-Hummaz formulation has been selected for the development of modern quality control standards with conventional parameters. The common and conventional quality control parameters such as organoleptic evaluations such as color, odor, taste, and consistency; physicochemical evaluations such as loss on drying, disintegration time for tablets, moisture content by Karl Fischer method, total ash, acid insoluble ash, water soluble ash, pH of 1% and 10% solution, extractive values, water soluble matter, alcohol-soluble matter, and total phenolic content along with thin layer chromatography (TLC) fingerprint have been carried out in triplicate.

Materials and Methods

Chemical and reagents

Preparation of Qurs-e-Hummaz formulation

Qurs-e-Hummaz is a tablet formulation, composed of the seven ingredients *R. vesicarius* Linn. (Seed), *B. bambos* Druce (bamboo manna), *R. damascena* Linn. (flower), *B. aristata* DC.(fruit), *C. lacca* (resin), *A. rotunda* Linn.(root), and *C. sativus* Linn. (root), which have been commonly used as an anti-inflammatory drug.

Three different batches of Qurs-e-Hummaz formulations were prepared by a qualified 'Hakim' (Unani medical practitioner) of Faculty of Unani Medicine, Hamdard University, as per the formula and instruction given in NFUM. The raw materials used for the preparation of the first batch were collected from Delhi region, the second batch from Chennai, whereas the third batch was obtained as gift samples from CCRUM Hyderabad unit. All the components used were identified by a qualified Botanist, which were further authenticated by pharmacognosist. The voucher specimens of all the raw materials used and formulations have been procured in Bioactive Natural Product Laboratory for further use.

Physicochemical evaluations

Qurs-e-Hummaz formulation was subjected to analysis according to the Unani Pharmacopoeia/Indian Pharmacopoeia and WHO/QCMMPM for parameters such as organoleptic study, disintegration time, loss on drying, moisture content, total ash, acid insoluble ash, water soluble ash, pH of 1% and 10% suspension, petroleum ether extractive value, chloroform extractive value, acetone extractive value, methanol extractive value, water extractive value, alcohol-soluble matter, water soluble matter, and total phenolic content by ultraviolet (UV).[5-8]

High performance thin layer chromatography fingerprinting of Qurs-e-Hummaz

High performance thin layer chromatography (HPTLC) was performed to develop fingerprint profiles of Qurs-e-Hummaz formulation.[9-12] Methanol, petroleum ether, and chloroform extracts were used for the fingerprint development. The methanol (100 mg mL^{-1}), chloroform and petroleum ether (160 mg mL^{-1}) extracts were prepared by sonicating 0.5, 0.8, and 0.8 g of Qurs-e-Hummaz in 20 mL of respective solvent for 30 min, followed by centrifugation to get the supernatant, which was concentrated under nitrogen, and further, the volume was adjusted to 5.0 mL using respective solvents.

High performance thin layer chromatography instrumentation and sample application

The HPTLC fingerprints of the different extracts of all drugs were established by developing the solvent systems for their separation by TLC. The solvent system in which maximum and well-resolved spots were found, selected for HPTLC. The samples were applied in triplicate (8.0 µL each), the width of the band was kept to 5.0 mm and distance between tracks was 13 mm on precoated silica gel 60 F_{254} plates (E. Merck, 0.20 mm thickness) using Linomat V (HPTLC sample applicator). The chromatograms were scanned at 254 and 366 nm wavelength followed by spectral analysis. Reprostar chromatography documentation apparatus was used for taking photographs of the HPTLC plates. Plates were also scanned at visual range after spraying visualizing reagent (anisaldehyde-sulfuric acid reagent).

Results

As the part of standardization procedure, the Qurs-e-Hummaz were tested for different physicochemical parameters such as organoleptic study, disintegration time, loss on drying, moisture content, total ash, acid insoluble ash, water soluble ash, pH of 1% and 10% suspension, petroleum ether extractive value, chloroform extractive value, acetone extractive value, methanol extractive value, water extractive value, alcohol-soluble matter, water soluble matter, and total phenolic content by UV [Table 1]. As from the results obtained from analysis of three different batches, a 'specification range' was prepared for the formulation. The preparation of such specification ranges for different physicochemical evaluation parameters will help pharmacognosist for assessing the quality of this formulation in any standardization laboratories.

The methanolic extract of Qurs-e-Hummaz has given 15 peaks when scanned at 450 nm after spraying with anisaldehyde-sulfuric acid reagent at the R_f 0.15, 0.19, 0.23, 0.27, 0.32, 0.39, 0.49, 0.54, 0.64, 0.69, 0.73, 0.77, 0.79, 0.86, and 0.95 using toluene: Ethyl acetate: Formic acid (5:6:1, v/v/v) as mobile phase. The chloroform extract of Qurs-e-Hummaz produced seven peaks on scanning at 450 nm after spraying with anisaldehyde-sulfuric acid reagent at R_f0.17, 0.24, 0.30, 0.35, 0.42, 0.57, and 0.68 using toluene: Ethyl acetate (9:1, v/v) as mobile phase. While the petroleum ether extract of Qurs-e-Hummaz

resulted in nine spots at R_f 0.20, 0.27, 0.32, 0.36, 0.42, 0.47, 0.56, 0.71, and 0.93 when scanned at 450 nm after spraying with anisaldehyde-sulfuric acid using benzene: Chloroform (1:4, v/v) as mobile phase [Figure 1]. The summary of TLC fingerprint is depicted in Table 2.

Table 1: Physicochemical evaluation of Qurs-e-Hummaz

Parameters	Observations ($n=3$)	Limits (lower-upper)
Color of the formulation	Brown	
Odor	Characteristic	
Taste	Bitter	
Consistency	Solid (tablet)	
Disintegration time (min)	26.67±1.4	24.0-27.0
Average weight (mg)	550±2.0	545-555
Dimensions (mm)	10.56±0.32	10.0-11.0
Diameter thickness	6.8±0.28	6.5-7.1
Loss on drying at 105°C (% w/w)	5.9	5.5-6.3
Moisture content by Karl Fischer method (% w/w)	5.33	5.0-6.0
Total ash (% w/w)	1.67±1.2	1.50-1.80
Acid insoluble ash (% w/w)	1.42±0.22	1.30-1.80
Water soluble ash (% w/w)	0.20±0.03	0.17-0.22
pH of 1% suspension	5.88±0.10	5.5-6.4
pH of 10% suspension	5.39±0.16	5.0-6.0
Petroleum ether extractive value (% w/w)	1.05±0.01	0.95-1.1
Chloroform extractive value (% w/w)	2.68±0.03	2.4-2.8
Acetone extractive value (% w/w)	6.43±0.33	6.1-6.7
Methanol extractive value (% w/w)	18.43±3.3	17.6-19.0
Water extractive value (% w/w)	9.32±0.77	8.7-9.9
Alcohol soluble matter (% w/w)	46.80±3.02	44.0-47.0
Water soluble matter (% w/w)	44.31±2.45	42.0-46.0
Total phenolic content by UV (% w/w)	3.24±0.72	3.0-4.0

UV – Ultraviolet

The evaluation of contaminants such as heavy metal content by atomic absorption spectrophotometer, determination of aflatoxins by HPLC and pesticide residues, by gas chromatography-mass spectrometry also have been carried out in all three batches of the formulations as per the methods described in AOAC.[13]

Discussion

As the part of standardization procedure, the Qurs-e-Hummaz was tested for different physicochemical parameters such as organoleptic study, disintegration time, loss on drying, moisture content, total ash, acid insoluble ash, water soluble ash, pH of 1% and 10% suspension, petroleum ether extractive value, chloroform extractive value, acetone extractive value, methanol extractive value, water extractive value, alcohol-soluble matter, water soluble matter, and total phenolic content by UV.

Even though India has a great tradition of indigenous systems medicine such as Ayurveda and Unani, there is a lack of thorough scientific exploration on the safety, quality and activity, compositions, and claimed indications. One of the main reasons behind this is the weak regulatory infrastructure for conventional pharmaceuticals on its safety, efficacy, and quality. Standardization of Qurs-e-Hummaz polyherbal

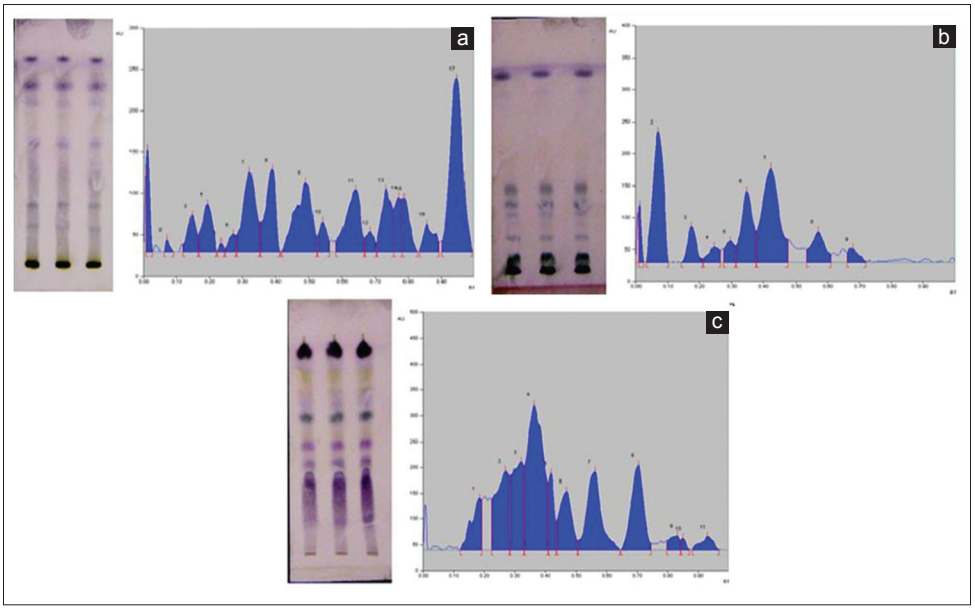

Figure 1: (a) Developed thin layer chromatography plate of methanolic extract of Qurs-e-Hummaz in daylight after spray and high performance thin layer chromatography chromatogram scanned at 450 nm; (b) developed thin layer chromatography plate of chloroform extract of Qurs-e-Hummaz in daylight after spray and high performance thin layer chromatography chromatogram scanned at 450 nm; (c) developed thin layer chromatography plate of petroleum ether extract of Qurs-e-Hummaz in daylight after spray and high performance thin layer chromatography chromatogram scanned at 450 nm

Table 2: Summary of thin layer chromatography fingerprints of the Qurs-e-Hummaz

		HPTLC fingerprint	
Extract	**Solvent system**	**Number of spots with R_f**	**Detection wavelength (after spray) (nm)**
Methanol	Toluene: ethyl acetate: formic acid (5:6:1)	(15) 0.15, 0.19, 0.23, 0.27, 0.32, 0.39, 0.49, 0.54, 0.64, 0.69, 0.73, 0.77, 0.79, 0.86, 0.95	450
Chloroform	Toluene: ethyl acetate (9:1)	(7) 0.17, 0.24, 0.30, 0.35, 0.42, 0.57, 0.68	450
Petroleum ether	Benzene: chloroform (1:4)	(9) 0.20, 0.27, 0.32, 0.36, 0.42, 0.47, 0.56, 0.71, 0.93	450

HPTLC: High performance thin layer chromatography

formulation was carried out using physicochemical and HPTLC fingerprint profiles. The results obtained through this study were reliable, quick, and reproducible and could be used for routine quality control analysis of the formulations. To take advantage of the increased demand of the traditional medicines in worldwide, India need to focus on developing a synchronized approach to standardize traditional medicine using modern quality control techniques. It could help in maintaining the quality and batch to batch consistency of many important polyherbal formulations.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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