Research Article

Comparative Physicochemical Evaluation of Qurse Tabasheer – In-House Preparation and Market Sample

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ABSTRACT

Background and objectives: Qurs (Tablet) is one of the most appropriate dosage form because of its accuracy, portability and stability of dose etc. Unani tablets consist of different types of crude drugs which need specific and standard manufacturing procedures for good quality of finished products to be maintained. In this work comparative study of in-house sample and market sample of Qurse tabasheer has been done on the basis of physicochemical parameters.

Methods: Different batches of *Qurse Tabasheer* were prepared as per method mention in national formulary of Unani Medicine and one ideal batch was selected. Final ideal selected batch (in-house) was compared with market sample of *Qurse Tabasheer* on the basis of various physicochemical parameters.

Results: Friability, hardness and disintegration time (in aqueous medium) of in-house sample and market sample was (0.09±0.0057 and 1.89±0.1817), (4.03±0.087 and 1.33±0.2333), and (25.57±0.4860 and 10.23±0.1524) respectively. Standards for loss of weight on drying, pH, total ash, water soluble, acid insoluble, and sulphated ash, extractive values total fungal, total bacterial counts and TLC were set in.

Conclusion: In-house sample shows better results in compression to market sample i.e. friability within permissible limit, accepted hardness and more number of TLC spots. Physicochemical standards were established by evaluation of *Qurse Tabasheer* which may be used for future reference.

Keywords: *Qurse Tabasheer*, Physicochemical, Hypoglycemic.

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INTRODUCTION

Throughout the preceding decade, use of traditional medicine has spread out worldwide day by day and has gained popularity. Plant, animal and mineral based natural pharmaceutical formulations have been outstanding outcomes in the treatment of human diseases. Safety and efficacy as well as quality control of herbal medicines and traditional procedure based therapies have become important concerns for both health authorities and the public. In this study a famous Unani formulation, named *Qurse Tabasheer;* has been taken, which is described in *Bayaaze Kabeer*, *Kitabul Murakkabat Al Maroof Makhzanul Murakkabat* and *Kitab Al Murakkabat*. It is a herbo-mineral formulation, having *Gulnar* (*Punica grantum* Linn), *Gule Surkh* (*Rosa damascene* Mill.), *Tukhme Khurfa* (*Portulaca oleracea* Linn.), *Tukhme Kahu* (*Lactuca sativa* Linn.), *Tabasheer* (*Bambusa arundinaceae* Retz.) *and Gile Armani* (Armenian Bole) in equal parts. This formulation is very effective in the treatment the treatment of *Dhayabitus* (Diabetes), *Is'hal* (Diarrhoea) and *Hummae Hadda* (Acute fever).[1-4] Comparative analysis has been established in in-house preparation and market sample for the physicochemical parameters, e.g. organoleptic properties, friability, tablet hardness, disintegration, extractive values, ash values, loss of weight on drying at 105°C, pH value, uniformity of diameter, weight variation and thin layer chromatography (TLC) etc.

MATERIALS AND METHODS

Collection of drugs and its identification

Gulnar, Gule Surkh, Tukhme Khurfa and *Tukhme Kahu* were procured from A.B. General Store, Avenue Road; Bangalore and identified by expert at FRLHT (Foundation for Revitalization of Local Health Traditions) Bangalore. *Tabasheer* was procured from a raw drug dealer 'Herbo World Associates', New Delhi, through A. B. General store, and identified by expert. Different samples of *Gile Armani* were collected from market and XRD was conducted for its identification at Department of Material Engineering, Indian Institute of Sciences Bangalore.

Method of preparation of in-house *Qurse Tabasheer*

After identification of the ingredients, the *Aqras* were prepared according to method mentioned in National Formulary of Unani Medicine with some modification[4]. Each batch of tablets was generated by 120 gm powder for the optimum working process related to the powder size (80,100,120 no. sieve), binder (Water, PVP, Gum acacia), granulation, temperature (60°C) and time (30 and 60 minutes) for drying, compression pressure (6 tons pressure) and post compression temperature and time (50° and 30 minutes) of *Qurs*. Prepared batches were assessed three times for physicochemical parameters for selection of ideal batch. Selection of final batch done on the basis of friability, hardness and disintegration time. Final selected batch have 100 no. sieve powder, binder gum acacia 20%, temperature and time of drying of granules 60°C and 60 minutes, compression pressure 6 tons, post compression drying at 50°C for 30 minutes.

Collection of market sample

Market sample of *Qurse Tabasheer* was purchased from local Unani drug supplier of Bangalore. Ideal selected batch was compared with market sample for physicochemical parameters.

Physicochemical Parameters:

1. **Organoleptic properties:** Appearance, Colour, Smell, Taste were evaluated.[5]
2. **Friability test:** For determination of friability of tablet Roche´s friabilator (Labinda mod. no. 1020) apparatus was used. This device subject the tablet to the combined effect of abrasion and shock in a public chamber revolving at 25 rpm and in each revolution dropping the tablets at a height of 6 inches. Tablets was placed in friabilator after weighing and subjected for 100 revolutions. Tablet de-dusted using a soft muslin cloth and reweighted. Calculate friability (%) by formula given below.[6,7]

   $F = (W_1 - W_2 / W_1) \times 100$ (W1= Initial weight of tablets, W2= Final weight of tablets)
3. **Tablet hardness test:** Three tablets were pickup randomly and they were separately tested for the hardness by Monsanto hardness tester (Shital scientific industries Sr.no. 11012010) in term of kg/cm^2. [6]
4. **Disintegration test**: For determination of disintegration time disintegration testing apparatus manufactured as per USP (TAB machine mod. no. TD 20S) was used. In apparatus there was 6 glass tube of length 3 inches, open at top and hold a mesh screen at bottom end of the basket rack assembly. In each tube of 2 basket rack assemblies of disintegration apparatus one tablet was placed and perforated plastic discs placed at top of the tablets and impart an abrasive action of the tablets. Basket rack was positioned in a one liter beaker filled with distilled water at 37°c ±2°c. The procedure was started for disintegration time for uncoated tablets. At last when tablets fully disintegrate and all particles of tablet pass through 10 no. mesh, then time of disintegration was noted.[8]
5. **Extractive values (Non successive):** The course powder of *Qurse Tabasheer* was extracted by Soxhlet apparatus individually in different solvent (water, ethyl alcohol and petroleum ether). 10 gm powdered drug was taken and subjected to separate extraction with each solvent. The then extracts were filtered by using filter paper (whatman No. 1) and evaporate on water bath. Extractive values were calculated with reference to drug taken (w/w). [9]
6. **Ash value**: Total ash and water soluble ash were conducted by method mention in protocol for testing.[10]

   Acid insoluble ash and sulphated ash were conducted by method mention in Unani pharmacopeia part II, volume I.[11]
7. **Loss of weight on drying at 105°C:** Loss of weight on drying at 105°C was conducted by method mention in Unani pharmacopeia part II, volume I.[11]
8. **pH value:** pH value of 1% solution and pH value of 10% solution was conducted by method mentioned in physiochemical standardization of Unani medicine part VI.[12]
9. **Uniformity of diameter:** Randomly three tablets was pickup to perform uniformity of diameter and the diameter of tablets was measured individually by using a vernier caliper (UTTAR, IME type 6 inch/15 cm) and expressed in mm.[13]
10. **Weight variation:** (USP weight variation test) Randomly 20 tablets were select from batch and weighing was done separately, average weight was calculated. Individual weights were compared to average weight. If not more than 2 tablets are outside the percentage limit, then tablets meet the USP test. [8]
11. **Thin layer chromatography:** Pre-coated plats of silica gel 60 F 254 (layer thickness 0.25 mm) on aluminum sheets was used, test was carried out for pet. ether, chloroform, methanol, ethanol and water extract of the *Qurse Tabahseer* . Used mobile phase Toluene: Ethyle acetate: Formic acid (5:4:1). Each extract was used for TLC test in above mentioned mobile phases.

Procedure: First of all TLC jar was taken, clean and dried and then selected mobile phase was poured into tank in sufficient quantity to form a layer of solvent 5-10 mm deep, tank is closed and allow to stand for one hour at room temperature for complete saturation of TLC jar environment. Extract solution was applied in the form of band (10-20 mm × 2-6 mm) on the line parallel with, and 20 mm above, from one end of the plate and not nearer than 20 mm to slide. After spotting, plate was put into saturated TLC jar vertically as possible and band was kept above level of mobile phase. Jar closed and allowed for standing at room temperature, until the mobile phase

ascended 3 /4th height of the plate, then plate was removed, dried and spot was observed. The plates were examined under U V light (254nm), detect the spots. After detecting spots Rf value was calculated by following formula.[14]

Rf value = Distance travelled by spot / Distance travelled by mobile phase.

12. Total fungal and specific pathogen like E. coli, Salmonella spp, S. aureus, Pseudomonas aeruginosa tests were done at Bangalore test house Bangalore by method mention in the Ayurvedic Pharmacopeia of India. Part II, Vol. 2nd ed. 1st.[15]

In-house prepared *Qurse Tabasheer*

Market sample of *Qurse Tabasheer*

RESULTS

1. **In in-house sample** organoleptic properties i.e. appearance, colour, smell, taste and texture were found to be tablets (slightly biconvex), dark brown, rosy, clayey, astringent, slightly bitter and hard. While **In market sample** organoleptic properties i.e. appearance, colour, smell, taste and texture were found to be tablets (slightly biconvex), brown, rosy, clayey, astringent, slightly bitter and medium hard. (Table 1)

Table 1:

Parameters	In-house preparation	Market sample
Appearance	Tablet	Tablet
Colour	Dark Brown	Brown
Smell	Rosy	Rosy
Taste	Clayey, astringent slightly bitter	Clayey, astringent slightly bitter
Texture	Hard	Medium Hard

2. The mean % age value of Friability of in-house and market sample were found to be 0.09±0.0057 and 1.89±0.1817 (Table 2)
3. The mean value of hardness of in-house and market sample were found to be 4.03±0.087 kg/cm and 1.33±0.2333 kg/cm. (Table 2)
4. The mean value of disintegration time of in-house sample in aqueous media and simulated gastric fluid were found to be 25.57±0.486 minutes and 24.72±0.1881 minutes. (Table 2)

The mean value of disintegration time of market sample in aqueous media and simulated gastric fluid were found to be 10.23±0.1524 minutes and 9.123±0.0731 minutes. (Table 2)

Table 2:

Physiochemical Parameters	Mean± SEM (In house sample)	Mean± SEM (Market sample)
Friability (%)	0.09±0.0057	1.89±0.1817
Hardness (Kg/cm)	4.03±0.087	1.33±0.2333
Disintegration time (mint.)		
Aqueous media	25.57±0.486	10.23±0.1524
Simulated gastric fluid (water with 0.1 M hydrochloric acid)	24.72±0.1881	9.123±0.0731
Total ash (%)	26.50±0.07638	18.6±0.1764
Water soluble (%)	0.8667 ± 0.07265	2.97±0.1908
Acid insoluble ash (%)	21.28 ± 0.3632	15.653±0.3768
Sulphated ash (%)	25.85 ± 0.2754	17.23±0.3500
Loss of weight on drying (105°) (%)	6.027 ± 0.1641	8.534±0.250
pH value at		
1%	5.450 ± 0.08021	5.55±0.3786
10%	4.727 ± 0.02404	4.72±0.0233
Uniformity of Diameter (mm)	13±00	16±00

5. The mean percentages of the non-successive extractive values of in-house sample were found to be 27.67 ± 0.5783, 13.48 ± 0.3398, 7.69 ± 0.3011 in water, ethyl alcohol and petroleum ether respectively. (Table 3)

   The mean percentages of the non-successive extractive values of market sample were found to be 20.93±0.4328, 9.63±0.2829 and 6.46±0.4339 in water, ethyl alcohol and petroleum ether respectively. (Table 3)

Table 3:

Solvents	Non-successive extractive values (%) (Mean± SEM) (In-house sample)	Non-successive Extractive values (%) (Mean±SEM) (Market sample)
Petroleum ether	7.69 ± 0.3011	6.46±0.4339
Ethyl alcohol	13.48 ± 0.3398	9.63±0.2829
Water	27.67 ± 0.5783	20.93±0.4328

6. In in-house sample mean percentage values of the total ash, water soluble ash, acid insoluble ash, sulphated ash were found to be 26.50±0.07638, 0.8667 ± 0.07265, 21.28 ± 0.3632, 25.85 ± 0.2754 respectively. (Table 2)

   In market sample mean percentage values of the total ash, water soluble ash, acid insoluble ash, sulphated ash were found to be 18.6±0.1764, 2.97±0.1908, 15.653±0.3768, 17.23±0.3500 respectively. (Table 2)

7. The mean % age value of Loss of weight on drying in in-house sample and market sample were found to be 6.027 ± 0.1641and 8.534±0.250. (Table 2)

8. The mean value of pH was determined at 1% and 10% solution of in-house sample were found to be 5.450 ± 0.08021and 4.727 ± 0.02404 respectively. While in market sample 5.55±0.3786 and 4.72±0.0233. (Table 2)

9. The mean value of diameter of in-house sample and market sample were found to be 13±00 mm and 16±00. (Table 2)

10. The mean value of weight of randomly selected 20 tablets in-house sample was found to be 793.7 ± 4.755 mg and the deviation of individual tablet weight from the average weight of 20 tablets was found within the percentage limit 5 % (Table 2). While of market sample mean value of weight of randomly selected 20 tablets was found to be 785.7 ± 4.215 mg and the deviation of individual tablet weight from the average weight of 20 tablets was found outside to the percentage limit 5 %.

11. **TLC of in-house sample:**

    Under Toluene: ethyl acetate: formic acid (5:4:1) mobile phase.

2 spots were found in petroleum ether extract, the Rf values were 0.76 and 0.84. 8 spots were found in ethanolic extract, the Rf values were 0.051, 0.11, 0.14, 0.27, 0.33, 0.42, 0.55 and 0.67, 7 spots were found in chloroform extract, the Rf values were 0.05, 0.09, 0.24, 0.33, 0.42, 0.55 and 0.66, 6 spots were found in methanol extract, the Rf values were 0.18, 0.23, 0.32, 0.40, 0.42 and 0.64, 5 spots were found in water extract, the Rf values were 0.09, 0.22, 0.28, 0.35and 0.44 (Table 4) (figure 1).

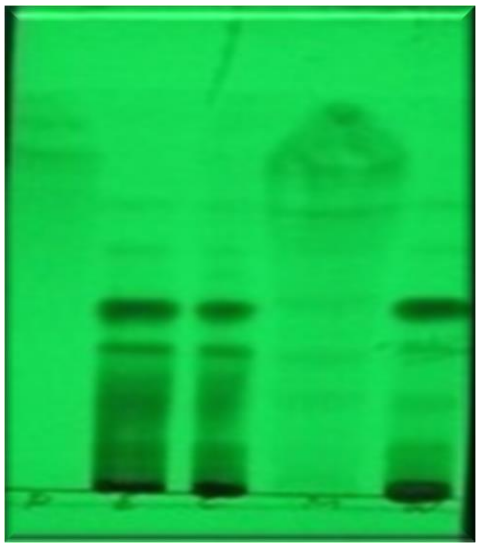

Figure 1: TLC of in-house sample

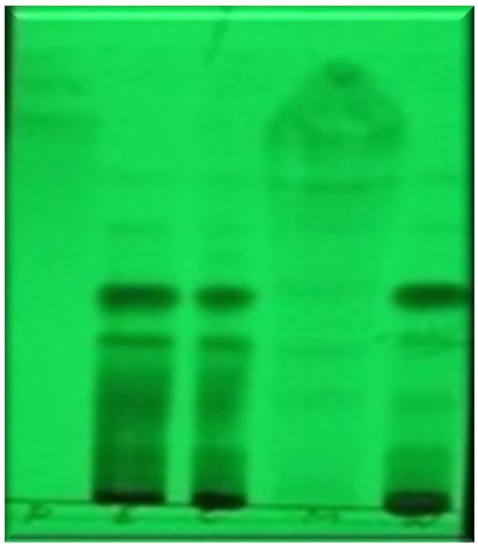

Figure 2: TLC of market sample

Photograph chromplate at 254 nm, From L→ R, Bands in extract of pet. ether, ethanol, chloroform, methanol and water in Toluene: Ethyl acetate: Formic acid (5:4:1) mobile phase.

12. **TLC of market sample:**

    Under Toluene: ethyl acetate: formic acid (5:4:1) mobile phase.

    2 spots were found in petroleum ether extract, the Rf values were 0.77 and 0.85, 7 spots were found in

ethanolic extract, the Rf values were 0.050, 0.11, 0.13, 0.27, 0.32, 0.42, and 0.68, 6 spots were found in chloroform extract, the Rf values were 0.05, 0.08, 0.25, 0.33, 0.43 and 0.69. 6 spots were found in methanol extract, the Rf values were 0.19, 0.22, 0.32, 0.41, 0.40 and 0.65, 4 spots were found in water extract, the Rf values were 0.09, 0.21, 0.27 and 0.45 (Table 4) (figure 2)

13. Total fungal and total bacterial count/g was found 190 CFU and 2100 CFU respectively. Specific pathogen like *E. coli, Salmonella spp, S. aureus, Pseudomonas aeruginosa* were found absent. (Table 5)

Table 4: TLC of in-house sample and market sample (mobile phase Toluene: ethyl acetate: formic acid (5:4:1)

Extract	Treatment	In-house sample	Market sample
		No. of spot Rf value	No. of spot Rf value
Petroleum ether	UV (254 nm)	2 1. 0.76 2. 0.84	2 1. 0.77 2. 0.85
Ethanol	UV (254 nm)	8 1. 0.051 2. 0.11 3. 0.14 4. 0.27 5. 0.33 6. 0.42 7. 0.55 8. 0.67	7 1. 0.050 2. 0.11 3. 0.13 4. 0.27 5. 0.32 6. 0.42 7. 0.68
Chloroform	UV (254 nm)	7 1. 0.05 2. 0.09 3. 0.24 4. 0.33 5. 0.42 6. 0.55 7. 0.66	6 1. 0.05 2. 0.08 3. 0.25 4. 0.33 5. 0.43 6. 0.69
Methanol	UV (254 nm)	6 1. 0.18 2. 0.23 3. 0.32 4. 0.40 5. 0.42 6. 0.64	6 1. 0.19 2. 0.22 3. 0.32 4. 0.41 5. 0.40 6. 0.65
Water	UV (254 nm)	5 1. 0.09 2. 0.22 3. 0.28 4. 0.35 5. 0.44	4 1. 0.09 2. 0.21 3. 0.27 4. 0.45

Table 5:

Parameters	Results (Inhouse sample)	Results (market sample)	Limits (As per API part II)
Appearance	Brown colour, circular flat uncoated tablets packed in a plastic container.	Ok	
Total fungus count/g	190 CFU	30 CFU	1000 CFU
Total Bacterial count/g	2100 CFU	1350 CFU	100000 CFU
E. coli/10 g	Absent	Absent	Absent
Salmonella spp./10 g	Absent	Absent	Absent
S. aureus/10 g	Absent	Absent	Absent
Pseudomonas aeruginosa/10 g	Absent	Absent	Absent

DISCUSSION

Analysis of both sample i.e. in-house sample and market sample was done by various physicochemical properties. In-house sample shows better results than market sample. Friability and hardness of in-house sample is within limit (0.09±0.0057 and 4.03±0.087) while market sample shows more friability then accepted limit and hardness below normal (1.89±0.1817 and 1.33±0.2333). It is an important parameter to measure the strength of tablets. So, because of less friability and more hardness, in-house sample have less chance of detoriation of tablets during manufacture, packaging, storage and transportation.[16] In-house sample and market sample have loss of weight on drying 6.027±0.1641 and 8.534±0.025. In-house sample has less moisture content so has less chance of bacterial and fungal infection. If any drug has more moisture level then this becomes ideal medium for growth of different types of bacteria and fungi. These bacteria and fungi affect the purity, quality and efficacy of drug.[17] The in-house sample shows more mean percentage of the non-successive extractive values in comparison to market sample. Extractive value of a drug in a definite solvent is an index of purity of a drug and plays a major role to determine adulteration.[18,19] TLC results in in-house sample shows more no. of spots then market sample that means poor quality of drugs used in manufacturing of market sample. Because of this some chemical constituents (no. of spots) missing in market sample. Total fungal and total bacterial counts in both i.e. in-house sample and market sample are within permissible limit.

CONCLUSION

Physicochemical standardization of in-house sample and market sample of Qurse Tabasheer shows that in-house sample shows better result in comparison to market sample. So Physicochemical standards of in-house sample of *Qurs Tabasheer* such as friability, hardness,

disintegration time, total ash, water soluble, acid insoluble, and sulphated ash, loss of weight on drying, pH and extractive values, were established by evaluation, which may be used as standards for future reference.

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