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Original Article

Development of Standard Operating Procedures (SOPs) of a Polyherbal Formulation *Quṛṣ-i Muṣaffī* Recommended for the Treatment of Skin Diseases

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ABSTRACT

Background: Despite increasing acceptability and effectiveness, Unani Medicine has been widely criticized for lack of quality assurance and poor presentation. Therefore, in order to ensure the production of high-quality drugs, good manufacturing practices and the development of scientifically Standard Operating Procedures (SOPs) are necessary. The purpose of this study was to create SOPs for a polyherbal formulation *Quṛṣ-i Muṣaffī* (QM) regarding its binder, temperature and duration of drying, as well as an assessment of its *Mizāj* (temperament). **Materials and Methods:** 18 batches of QM were prepared under different conditions (binder, temperature and duration of drying). Powder of particle sizes 150 µm, gum acacia mucilage (10%, 15% and 20% w/w) were used as a binder, at 60°C temperature for 20 and 30 min during the process of granulation and after compression 20 min only. **Results:** Data of the study revealed that the final batch of QM with particle size 150 µm, gum acacia (20 %) as the binder, temperature 60°C for 30 min for granules and 20 min after compression were found appropriate. The temperament (*Mizāj*) of the QM was assessed through method described by renowned Unani scholar *Al-Kindī* and found to be moderate degree in hot property and second degree in dry property. **Conclusion:** The obtained results of final batches of QM can be adopted as the SOPs for future references in terms of process standardization and reproducibility of the drug.

Keywords: *Mizāj*, Quality Control, *Quṛṣ-i Muṣaffī*, SOPs, Unani System of Medicine.

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INTRODUCTION

India has a very distinctive position globally in area of herbal medicine and herbal products, where a number of Government recognized traditional healthcare systems, including Unani, Ayurveda, Yoga and Naturopathy, Siddha and Homeopathy are being used to treat human's health effectively. India is also known as "Medicinal garden of the world" due to its largest production of natural herbs, which have less or minimal side effects, cost effective, easy availability, increased demand for herbal medicines, pharmaceuticals, health products, cosmetics, food supplements, etc.[1-3] Nowadays, herbal industries increasing their scope very fast in the international market, but unluckily India cannot achieve remarkable performance in the international trade of herbal industry especially with reference to the Unani System of Medicine (USM) because of lack of scientific approach, insufficient scientific data for manufacturing of *Quṛṣ* (tablet) and other finished products and poor quality presentation of drugs and dosage forms. In turn, the utilization of Good Manufacturing Practices (GMPs) as well as the development of Standard Operating Procedures (SOPs) in the manufacturing of herbal drugs have become utmost important elements for ensuring their good quality presentation, efficacy and safety.

SOP was described by various authors in different ways. It is defined as "a set of written and comprehensive regulations that demonstrate a routine and repetitive activity followed by an organization to achieve uniformity of performance of a particular function" by the US Environmental Protection Agency and the European Medicines Agency.[4] "SOP is a set of written guidelines that assist participants working in a specific setting in

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Table 1: Composition and excipients used in preparation of *Quṛṣ-i Muṣaffī*.

S. No.	Unani Name of Ingredients	Botanical Name (s) (Family)	Part Used	Quantity	Role
1	*Chāksū*	*Cassia absus* L. (Leguminosae / Fabaceae)	Seeds	Equal	Active drug
2	*Rasaut*	*Berberis aristata* DC. (Berberidaceae)	Root extract	Equal	Active drug
3	*Neem*	*Azadirachta indica* A. Juss. (Meliaceae)	Seeds' kernel (*Maghz-i Neem*)	Equal	Active drug
4	*Ṣamagh-i 'Arabī*	*Acacia arabica* (Lam.) Wild. (Leguminosae)	Gum	20 % of total drug weight	Binder
5	Water (Purified)			For making *Lu'āb* / *lubdī* (wet massing)	

correctly carrying out specific procedures". The implementation of SOPs in the pharmaceutical industry is essential to achieving the desired quality end result and homogeneity in accordance with good practice guidelines.[5]

Quṛṣ-i Muṣaffī is an important and highly recommended polyherbal Unani formulation used in various skin diseases (*Amrāḍ-i Jild*) selected from kit medicine list developed by the Central Council for Research in Unani Medicine (CCRUM), Ministry of AYUSH, Government of India.[6] It contains three ingredients e.g., *Azadirachta indica* A. Juss. (*Neem*), *Cassia absus* L. (*Chaksu*) and *Berberis aristata* DC. (*Rasaut*), which all have blood purifier action. *Neem* is used in many skin diseases (*Amrāḍ-i Jild*) e.g., itching, tinea, syphilis, leprosy, nonhealing ulcers and various inflammatory conditions.[7] While *Rasaut* is effective in *Nār Fārsī* (eczema), *Namla-i Khabitha* (worst herpes) and burning by dry heat. It is also useful in *Kalaf* (melasma/ chloasma), *Dākhis* (paronychia/whitlow) and other skin diseases.[8,9] Similarly, the seeds of *Chāksū* are also considered very effective in tinea and other skin infections.[10]

In USM, the concept of *Mizāj* (Temperament) is a fundamental theory for knowing status of health and disease of human beings and it is also necessary for the selection of either single or compound drugs in accordance with disease condition that is reversing the abnormal temperament (*Mizāj*) to the normal, by using drugs of opposite temperament (*Mizāj*) for curing the disease.[11] Every substance of plant, animal as well as mineral origin has its own *Mizāj* which indicates the possible actions of drugs in the body, doses and duration for which drug can be used for long time by the patient. For example, the drugs of the third and fourth degrees of temperament cannot be used in high doses or for extended period of time, whereas drug of the first and second degrees can be used safely for extended periods of time also with no or minimal adverse effects on the body.[12] QM is a compound Unani formulation which has three ingredients and each ingredient has its own temperament.

All of the aforementioned issues must be addressed in order to produce high quality tablets and also other Unani finished products that are both safe and effective in the various diseases for which they have been recommended. Hence, in this study, the development of SOPs of QM considering various steps of its manufacturing method, including binder quantity in %, temperature and duration of drying, supporting data of different processes associated with the preparation of QM were also done in order to achieve optimum friability, hardness, disintegration time, and other production standards. Assessment of *Mizāj* was also evaluated.

MATERIALS AND METHODS

Procurement and authentication of ingredients of polyherbal Unani formulation QM

The polyherbal Unani formulation QM has been selected from the kit medicine list of CCRUM, Ministry of AYUSH, Govt. of India and the ingredients (crude drugs) of QM *viz*., *Chāksū, Rasaut* and *Maghz-i Neem* were procured from GMP certified pharmacy of the National Research Institute of Unani Medicine for Skin Disorders (NRIUMSD), Hyderabad, Telangana. The crude drugs of QM were identified and authenticated at Survey of Medicinal Plants Unit (SMPU), NRIUMSD, Hyderabad and a voucher specimen number for *Chāksū*- SMPU/CRI-Hyd14334, *Rasaut*- SMPU/CRI-Hyd14335, *Neem*- SMPU/CRI-Hyd14336 were allotted. The composition and excipients of formulation QM are given in the Table 1.

Development of Standard Operating Procedures (SOPs) of QM

Instruments used

Weighing machine (Sartorius, Germany), pulverizer machine, iron mortar and pestle, sieve no. 100, hot air oven (Shital Scientific Industries, Mumbai, India), tablet punching machine, Roche's friability test apparatus (TIA, Nagpur, India), disintegration

Table 2: Batches of *Quṛṣ-i Muṣaffi*.

Batch No.	Method of preparation					
	Sieve No.	Particle size (µm)	Binder (%)	Temperature of drying of granules (°C)	Duration of drying of granules	Post compression drying at 60°C
1	100	150	10	60	20	20 min
2	100	150	10	60	30	20 min
3	100	150	15	60	20	20 min
4	100	150	15	60	30	20 min
5	100	150	20	60	20	20 min
6	100	150	20	60	30	20 min
7	100	150	10	60	20	20 min
8	100	150	10	60	30	20 min
9	100	150	15	60	20	20 min
10	100	150	15	60	30	20 min
11	100	150	20	60	20	20 min
12	100	150	20	60	30	20 min
13	100	150	10	60	20	20 min
14	100	150	10	60	30	20 min
15	100	150	15	60	20	20 min
16	100	150	15	60	20	20 min

testing apparatus, Monsanto hardness tester (Shital Scientific Industries, Mumbai, India). These instruments were appropriately calibrated before use.

Detection of foreign matter in crude drugs

All ingredients of QM were examined and cleaned carefully by inspection with naked eyes and all foreign matter was removed.

Method or process of preparation of QM

The polyherbal Unani formulation QM was prepared according to its composition at the GMP certified pharmacy of NRIUMSD, Hyderabad, as per procedure mentioned in National Formulary of Unani Medicine (NFUM)[13] and Unani Pharmacopoeia of India (UPI).[14] As per the Unani classics, two ingredients of this formulation (*Chāksū* and *Rasaut*) must be detoxified (*Mudabbar*) before adding in any compound. So, that the detoxification (*Mudabbar*) of *Chāksū* and *Rasaut* was done properly.[15] After identification, detection of foreign matter and detoxification (*Mudabbar*) of the ingredients of QM, the *Aqrāṣ* (tablets) were prepared. Various batches of *Aqrāṣ* (tablets) were generated with 120 g of powder in each batch for the optimum working process, which were associated to the binder, granulation, temperature, drying time and compression of *Aqrāṣ* (tablets). Each batch was evaluated three times with the records of various steps of the manufacturing process (Table 2 and Figure 1).

Step 1. Weighing, powdering and sieving of raw drugs.

Weighing of all single drugs in an equal quantity is done by the help of a digital weighing machine as per the composition mentioned in Table 1. Detoxified (*Mudabbar*) *Chāksū* and *Rasaut* mix with *Maghz-i Neem* and powdered in a pulverizer to obtain uniform powder and sieved through a 100 number sieve.

Step 2. Use of binders and preparation of binder solution.

As per NFUM, various binders can be used for the preparation of tablets (*Quṛṣ*).[13] So, *Ṣamagh-i 'Arabī* (gum acacia) was selected as the binding agent for preparation of different batches of QM. Binder *Ṣamagh-i 'Arabī* (gum acacia) was used at concentrations of 10, 15, and 20 percent of the total powder weight. For the preparation of mucilaginous suspension, water (purified) and binder (*Ṣamagh-i 'Arabī*/gum acacia) in the ratio of - 6:4 w/w were taken and both of them were put in a beaker and stirred frequently until the gum was dissolved properly.[16]

Step 3. Granulation.

Preparation of *lubdī* (wet mass): The wet mass was prepared by adding binder solution (mucilaginous suspension) to the powdered drug material with a sufficient amount of water and the prepared wet mass was mixed in a mixer grinder for its homogeneity.

Figure 1: Active ingredients of *Qurṣ-i Muṣaffi*.

Preparation of Granules: 20 number mesh sized granules were prepared with the help of a planetary oscillating granulation machine.

Drying of granules: Prepared granules were dried for 30 min at 60°C for all batches in a hot air oven.

Step 4. Compression.

The dried granules obtained were subjected to compression by multi-station rotary presses (tablet punching machine) at six tone compression for the preparation of 500 mg each tablet of all batches.

Step 5. Drying of tablets.

Prepared tablets were dried for 30 min at 60°C for all batches (Figure 2).

Step 6 Storage

As per NFUM, the prepared tablets *(Qurṣ)* were preserved in well dried, clean and airtight glass containers and stored in a cool and dry place, protecting from light.[13]

Assessment parameters of all batches of QM

Determination of hardness of QM (tablets)

Nine tablets were randomly selected in three batches for evaluation of hardness by a Monsanto hardness tester. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger was pushed against the tablet as well as a 0 (zero) reading was obtained. By turning a threaded bolt, the upper plunger was allowed to force against a spring until the tablet fragmented. A pointer rides along a gauge in the barrel to indicate the force applied as the spring compresses. The force of fracture was recorded, and the zero-force reading was deducted from it. Hardness was performed on nine tablets in three batches in all instances, and the average values of each batch were recorded.[17]

Friability of QM (tablets)

The friability of QM has been calculated with the help of Roche's friability test apparatus. This testing machine subjected the tablets to both effects rubbing and shock testing in a plastic chamber rotating at 25 rpm and falling the tablet at a height of six inches in each rotation. Pre-weighed specimen of tablets was put in the friability apparatus and applied to 100 spins. The tablet was

de-dusted with the help of a soft muslin cloth and re-weighed. The friability (f) is calculated by the following formula:

$$\text{Friability \% of QM (f)} = \frac{W_1 - W_2}{W_1} x100$$

Where W_1 denotes the weight of the tablets prior to the test and W_2 denotes the weight of the tablets following the test. This process was repeated three times, and the mean value was calculated. Values of "f" from 0.5 to 1.0% are regarded as the upper limit of acceptability.[17,18]

Determination of Disintegration time of QM (tablets)

The disintegration time of tablets was determined with the help of a double six-cylinder basket rack assembly. This disintegration testing apparatus was manufactured as per the United State Pharmacopoeia (USP). The above USP device for testing tablet disintegration has six glass tubes that are three inches long, open at the top side, and held against a 10-mesh screen at the basket rack assembly's bottom end. To test for disintegration time, one tablet was placed in each tube of two basket rack assemblies of disintegration apparatus and perforated plastic discs were placed on top of the tablets in each cylinder because it imparts an abrasive action on the tablets is produced by this disc, and the basket rack was placed in a beaker (one litter) filled with distilled water at 37°C ± 2°C, such that the tablets continue to stay 2.5 cm below the surface of fluid on their upward motion and descend not closer than 2.5 cm from the bottom of the beaker. At a frequency of 28 to 32 cycles per minute, a standard motor-driven device was used to move the basket assembly containing the tablets up and down a distance of 5 to 6 cm. The tablets must disintegrate and all particles must pass through the 10 number mesh screen, then the time of disintegration was noted. Uncoated USP tablets have a disintegration time of 5-30 min. The readings were taken three times, and the average values were noted.[17]

Figure 2: Final batch of *Qurṣ-i Muṣaffi*.

Weight Variation of QM (tablets)

20 (Twenty) tablets were selected at random and individually weighed then the average percentage was determined and compared the individual tablets' weight to the average. The tablets meet the USP test (if not more than two tablets fall outside the percentage limit or if not two tablet differs by more than twice the percentage limit). The weight variation tolerances for uncoated tablets differ depending on average tablet weight, QM was found in more than the 324 mg category.[17]

Temperament (Mizāj) Assessment of QM (tablets)

As per renowned Unani scholar *Al-Kindī* (d. 873 C.E.), assessment of *Mizāj* of a compound formulation should be done by the following method. Arrange all qualities (*Ḥarārat* [Hotness], *Burūdat* [Coldness], *Ruṭubat* [Moist/wetness], *Yabūsat* [Dryness]) of drugs separately and taken sum, then minus within the same quality (active property [*Kayfiyt-i Fa'ila* means Hot and Cold] to the active property and passive property [*Kayfiyt-i Munfa'ila* means Moist and Dry] to the passive property). After that, the obtained value(s) will be divided by the total number of ingredients present in the formulation.[19]

RESULTS

Hardness Test

The mean percentage of hardness of QM was found in the range of 8±0.15 to 9±0.11 kg/cm^2 in the final three different batches. The data for hardness test is graphically represented in the Figure 3 and Table 3.

Friability Test

The mean percentage of friability values of QM was found in the range of 0.1223±0.0006 to 0.1280±0.0009% in the final three different batches. The data for friability is graphically represented in the Figure 3 and Table 3.

Disintegration time of (QM) tablets in aqueous medium

The mean values of the disintegration time of QM in aqueous medium were found 22±1.0 to 22±0.57 min in the final three different batches. The data of disintegration time is graphically represented in the Figure 4 and Table 3.

Weight Variation of QM (tablets)

The average value of randomly selected twenty tablets for weight variation was found to be 500±9.9578 mg. The deviation of individual tablet weight from the average weight of twenty tablets was found to be 1.5±1.2640 (within the 5% limit). The data of weight variation of QM is represented in the Table 4.

Temperament of QM (tablet)

The total sum of degree of hot and cold is obtained 3 (three) and 2 (two) respectively. The sum of cold is subtracted from the sum of hot, which shows a final value of 1 (one). Then, this value is divided by the number of total ingredients (three) and gives a value of 0.33, which indicates hot in first degree. Similar manner, the sum of moist and dry is obtained 0 (zero) and 5 (five) respectively. So, this value (five) is divided by the number of ingredients (three) and gives a value of 1.66, which indicates dry in second degree. Consequently, the *Mizāj* of QM was assessed as moderate in Hot (*Ḥār Muʿtadil*) and dry in second degree (*Yābis* 2°). *Mizāj* (temperament) assessment of QM depicted in Table 5.

DISCUSSION

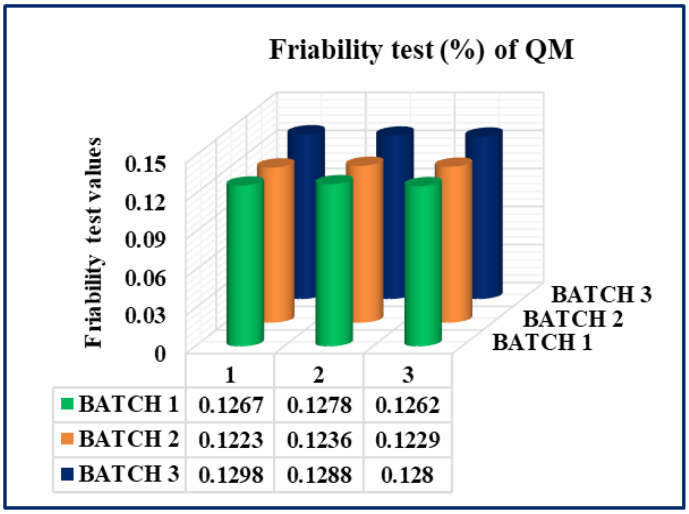
Unani medicines are very efficacious in various diseases, especially in chronic diseases but have not been able to achieve their importance in the global market due to lake of SOPs and standardization of formulations, which affect the quality, safety and efficacy of drugs. So, three variables, i.e., binder, temperature and duration of drying were taken into consideration in order to establish the SOPs of QM.

In this study, 18 batches were prepared with three different percentage (10,15, 20%) of binders to develop SOPs. It starts with the powdering of drugs, which should be done after the mixing of all three ingredients, because *Maghz-i Neem* has oil content, which creates a problem (sticking in the pulverizer machine) during powdering. Hardness, friability and disintegration time of the tablets are all affected by the binder, temperature, and drying duration. Hardness and disintegration time increase if the percentage (%) of binder increases, whereas friability decreases.[20,21] Among 18 batches of QM, six batches with 10% binder (batch nos. 1, 2, 7, 8, 13, & 14) are totally out of acceptable limits in respect of all three variables (hardness friability and disintegration time), other six batches (batch nos. 3, 4, 9, 10, 15 & 16) with 15% binder are within the acceptable limits in respect of hardness and disintegration time but friability not within acceptable limit and rest six batches (5, 6, 11, 12, 17 and 18) with 20% binder are within acceptable limits but three batches of them, i.e., 5, 11 and 17 are not good in quality, while three batches, i.e., 6, 12 and 18 are very good in quality. But batch number 12 was selected as the final batch, because it had the lowest friability, higher hardness and reliable disintegration time.

Hardness test means the force required to break the tablet in a diametric compression test. It has a direct affection on tablet disintegration and dissolution. Very hard tablets will have a longer disintegration time that will ultimately slow down the dissolution process and subsequently impaired absorption of the drug while too soft tablets will not be able to withstand the mechanical pressure of packaging, shipping and transport. Tablets for oral use typically have a hardness of 4 to 10 kg/ cm^2.[22] The mean percentage of hardness of QM was found in the range of 8±0.15 to 9±0.11kg/cm^2 in three different batches, which was within the limit. It is graphically represented by Figure 3.

Friability test of tablets is an important measure to evaluate the physical strength of compressed and uncoated tablets upon exposure to mechanical shock and attrition during their manufacturing, distribution, transportation and handling. In the conventional system of medicine, compressed tablets that lose less than 0.5% to 1% of weight are considered acceptable.[18] The mean percentage of friability of QM was found to be in the range of 0.1223±0.0006 to 0.1280±0.0009 % among three different batches of the formulation which was within the permissible limit. It is graphically represented by Figure 3.

Disintegration time is useful as a quality assurance tool and as a measure of stability for solid dosage forms. According to USP (United States Pharmacopeia) uncoated tablets have a disintegration time standard of 5 to 30 min when placed in a liquid medium.[23,24] The mean value of disintegration time of QM



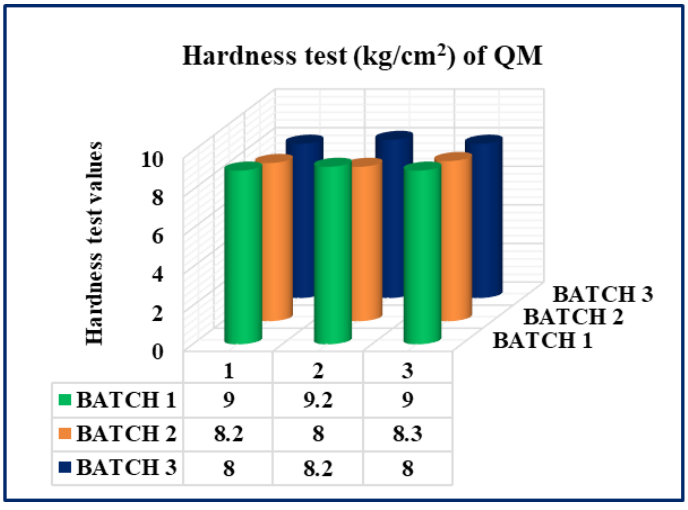
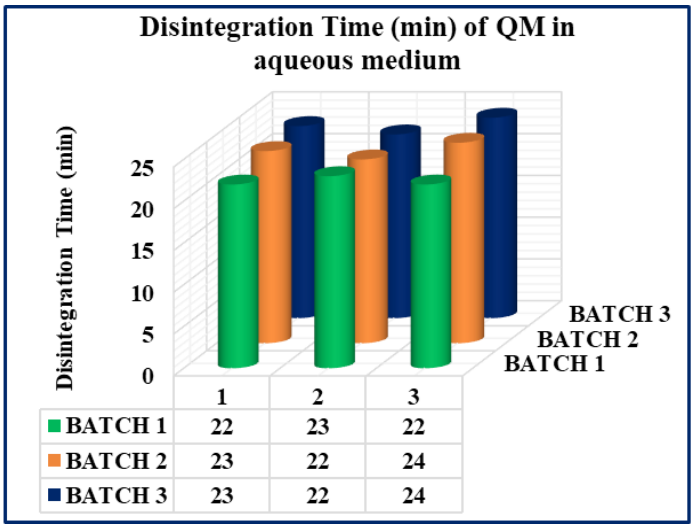


Figure 3: Hardness and friability tests of final batch of QM.

Table 3: Results of all batches of *Quṛṣ-i Muṣaffi.*

B. No.	Sieve No.	Particle size (µm)	Binder GAM* (%)	Duration of drying granules at 60°C	Post-compression drying at 60°C	Hardness (kg/cm²) Mean ± SD	Friability (%) Mean ± SD	Disintegration Time (Minutes) Mean ± SD
1	100	150	10	20 min	20 min	2±0.11	7±0.16	3.5±1.0
2	100	150	10	30 min	20 min	2.4±0.57	7.5±0.50	4±0.57
3	100	150	15	20 min	20 min	4.20±01	3± 0.20	16±0.30
4	100	150	15	30 min	20 min	5.60±01	2.5±0.57	17±0.50
5	100	150	20	20 min	20 min	8.60 ± 0.5	0.1630±0.0005	21±20
6	100	150	20	30 min	20 min	8.2±0.15	0.1252±0.0008	218±0.57
7	100	150	10	20 min	20 min	2±0.11	7±0.16	3±1.0
8	100	150	10	30 min	20 min	2.5±0.57	7.5±0.50	4±0.57
9	100	150	15	20 min	20 min	4.70±0.40	3.±0.20	16.30±0.40
10	100	150	15	30 min	20 min	5.30±0.60	2.5±0.57	17.10±0.20
11	100	150	20	20 min	20 min	8.70±0.50	0.1430±0.0008	22±0.20
12	100	150	20	30 min	20 min	9±0.11	0.1223±0.0006	22± 1.0
13	100	150	10	20 min	20 min	2±0.25	7±0.16	3.5±1.0
14	100	150	10	30 min	20 min	2.5±0.35	7.5±0.57	4.4±1.0
15	100	150	15	20 min	20 min	4.80±0.40	3±0.20	17.30±0.40
16	100	150	15	30 min	20 min	5.40±0.50	2.5±0.57	16.10±0.20
17	100	150	20	20 min	20 min	8±0.11	0.1521±0.0002	21±0.30
18	100	150	20	30 min	20 min	8.5±0.11	0.1280±0.0009	22±1.0

GAM*= Gum Acacia Mucilage



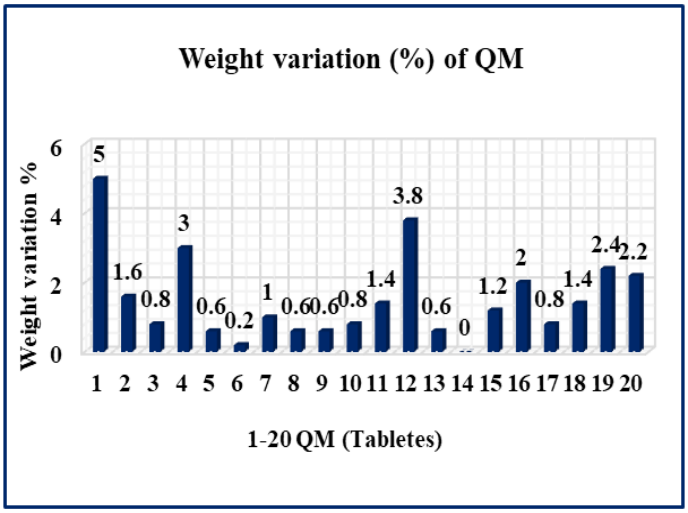


Figure 4: Disintegration time and weight variation of final batch of QM.

in aqueous media was found 22±1.0 to 22±0.57 min in three different batches, which is good in comparison to the maximum permissible limit of 30 min. It is graphically represented by Figure 4.

Weight variation of (QM) tablets is an important tool to ensure good manufacturing practices (GMP), appropriate size of the tablets and the content uniformity of the formulation.[25] The average values of randomly selected twenty tablets of 3 batches were found to be 500±9.95 mg. The deviation of individual tablet weight from the average weight of twenty tablets was found 1.5±1.2640 within the 5% limit,[17] that is depicted in Table 5 and graphically represented in Figure 4.

Table 4: Weight variation of *Qurṣ-i Muṣaffī* (tablets).

S. No.	Individual tablet (Qurṣ) weight in mg	Difference in weight of individual Qurṣ (Tablet) and average weight (mg) of Qurṣ (variation)	Weight variation %
1	525	25	05
2	492	08	1.6
3	496	04	0.8
4	485	15	03
5	497	03	0.6
6	501	01	0.2
7	505	05	01
8	503	03	0.6
9	503	03	0.6
10	504	04	0.8
11	507	07	1.4
12	481	19	3.8
13	497	03	0.6
14	500	00	00
15	506	06	1.2
16	510	10	02
17	504	04	0.8
18	507	07	1.4
19	488	12	2.4
20	489	11	2.2
Average± SD	500±9.9578		1.5±1.2640

Table 5: *Mizāj* (temperament) assessment of *Qurṣ-i Muṣaffī*.

S. No.	Ingredients	*Kayfiyāt-i Arba'a* (four physical properties)			
		Kayfiyāt-i Fa'ila (active properties)		*Kayfiyāt-i Munfa'ila* (passive properties)	
1	Chāksū	*Ḥār*$^{2^\circ}$ (Hot$^{2^\circ}$)	*Bārid* (Cold)	*Raṭab* (Moist)	*Yābis*$^{2^\circ}$ (Dry$^{2^\circ}$)
2	Rasaut	*Ḥār* (Hot)	*Bārid*$^{2^\circ}$ (Cold$^{2^\circ}$)	*Raṭab* (Moist)	*Yābis*$^{2^\circ}$ (Dry$^{2^\circ}$)
3	Neem	*Ḥār*$^{1^\circ}$ (Hot$^{1^\circ}$)	*Bārid* (Cold)	*Raṭab* (Moist)	*Yābis*$^{1^\circ}$ (Dry$^{1^\circ}$)
Sum		3	2	0	5
Result		3-2 =1, 1/3=0.3333 means Hot in Moderate degree (*Ḥār Mu'tadil)*		5/3=1.66 means *Yābis2°* (Dry2°)	
Final *Mizāj* of formulation QM		Moderate in Hot (*Ḥār Mu'tadil)* and Dry in 2° (*Yābis in 2°*)			

The drug's temperament (*Mizāj*) is significant in deciding the dose and its pharmacological properties. The temperament (*Mizāj*) of QM was found moderate in Hot (*Ḥār Mu'tadil*) and dry in second degree [*Yābis*$^{2^\circ}$]. The recommended dose of QM is 2 tablets (500 mg) thrice a day.

CONCLUSION

The current study data revealed that the batch having particle size 150 µm (100 No. sieve), gum acacia (*Ṣamagh-i-'Arabī*) 20% as a binder and dried at 60°C for 30 min for granules and 20 min after compression is the final batch and can be adopted as the SOPs for future references in terms of process standardization

and reproducibility of the study formulation. The data may also be useful in future studies to determine regulatory prospective to ensure the quality of Unani medicine. Furthermore, *Mizāj* (temperament) of QM is useful in determining its dose, quality, and therapeutic values.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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