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Standardization of a non pharmacopoeial majoon used in unani medicine

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ABSTRACT

Background: Proper identification & standardization is mandatory to ensure the therapeutic efficacy of herbal drugs used for health ailments. All single drugs and compound formulations should be standardized according to the guidelines of Pharmacopeia to ascertain their quality standards. Aim of the present study is to standardize and to assure the quality of a Unani Non Pharmacopoeial Majoon (NPM) used for various liver diseases.

Material and methods: Standardization was made on the basis of physicochemical and analytical parameters laid down by National Unani Pharmacopoeia Committee.

Results: The parameters studied includes alcohol soluble content 11.46±0.446, water soluble content 19.47 ±1.120, successive extractive values viz. petroleum ether 0.683±0.025, diethyl ether 0.193±0.01, chloroform 0.589±0.011, ethanol 53.926±2.27, and aqueous 14.363±1.36, total ash 1.83±0.166 , acid insoluble ash 0.66±0.166, water soluble ash 1.3±0.05, moisture content 12.1±0.42, specific gravity 1.282±0.026, viscosity at 70% 603.833±22.540, pH values of 1% solution 6.306±0.24 and 10% solution 9.28±0.193. The qualitative analysis of various phytochemicals was estimated that revealed the presence of phenols, tannin, sterols/terpens, flavonoids and reducing sugar. The TLC profile of the extracts of non pharmacopoeial majoon was also performed which confirms various biomolecules in it.

Conclusion: This study helps in determining the quality and purity of majoon which is use in various liver ailments like hepatitis, jaundice, ascites, cirrhosis etc.

Keywords: Standardization, Non-Pharmacopoeial Majoon, Compound Formulation, Physico-chemical study.

INTRODUCTION

Standardization is pre-requisite in quality control of single as well as compound drug. Quality evaluation is a fundamental requirement of industry and other organizations dealing with local traditional medicines and herbal products (Syed et al., 2014). So it is very necessary to standardize compound formulations in order to check the purity, genuineness and optimum therapeutic efficacy of a preparation (Zameer, 2013). It is essential to assess of quality of drugs which is based on the concentration of their active principles, physic-chemical property, phyto-chemical constituents and various other in-vitro and in-vivo parameters. Quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in the present system of medicine. It also requires implementation of Good Manufacturing Practices/GMP (Rasheed et al., 2012). The safety and efficacy of a polyherbal pharmaceutical formulation depends upon the authenticity of raw material. Sub-standard drugs effect adversely the reputation of physician and cause more harm than good to the patient (Chopra et al 1958). With the objective of Standardization present study was designed to standardize a Non-Pharmacopeial Majoon (NPM) used in various liver ailments and is made up of ten ingredients (Table-1). Therefore, the standardization of its ingredients was also considered to be mandatory.

MATERIAL AND METHOD

In the present study a Non pharmacopoieal Compound formulation-Majoon (NPM) was standardized and its physico-chemical values were established.

Collection of material

Ingredients of the NPM were procured from Dwakhana Tibbiya College, AMU, Aligarh and were identified and authenticated in the Pharmacognosy section of Department of Ilmul Advia, Faculty of Unani Medicine,

AMU Aligarh and Majoon was prepared from the same constituents.

Table 1. List of Ingredients of NPM.

S.N.	Unani Name	Amount	Botanical name	Family	Part used
1.	Gul-e-surkh	30 gm	*Rosa damascene* Mill.	Rosaceae	Flower
2.	Rewandchini	10 gm	*Rheum emodi* Wall.	Polygonaceae	Rhizome
3.	TajQalmi	10 gm	*Cinnamomum cassia* Blume.	Lauraceae	Bark
4.	Balchad	10 gm	*Nardostachys jatamansi* DC	Valerianaceae	Root
5.	Kasni	10 gm	*Cichorium intybus* Linn.	Compositeae	Seed
6.	Punarnawah	10 gm	*Boerhavia diffusa* Linn.	Nyctaginaceae	Root
7.	Asarun	10 gm	*Asarun europoeum*Linn.	Aristolochiaceae	Root
8.	Irsa	10 gm	*Iris ensata* Linn.	Iridaceae	Root
9.	Zafran	3 gm	*Crocus sativus* Linn.	Iridaceae	Stigma, Style
10.	Luk-e-Maghsool	10 gm	*Lacciferlacca* Kerr.	Lacciferidae	Resinous secretion

Method of preparation of majoon

The Majoon was prepared according to the standard method described in National Formulary of Unani Medicine, 2007. Before preparation of majoon the single plant drugs of formulation was dried in oven at different temperatures such as roots and barks at 50˚- 60˚C, flowers and seeds at 20˚-40˚C (Afaq et al., 1994). After that the drugs were cleaned and crushed to make fine powder in electric grinder at 80 meshes sieves except Luk and Zafran.

Purification of Luk/Luk-e-Maghsool

Lac was cleared from the pieces of wood and straw. Then decoction of *Andropogans chaenar* (Izkhar) and *Rheum emodi* (Revandchini) was added gradually. After that solution was decanted. The residue left behind, was again powdered in fresh decoction and decanted. Process was made continue till no residue left. Now solution was allowed to remain undisturbed, till fine powder obtained. It was again decanted and dried (Antaki 2008, Momin 1272H). In this way, pure fine powder of Lac that is Luk-e-Maghsool was obtained.

Preparation of Qiwam (Consistency)

The Qiwam (base) was made by adding Aab (water) in the base of sugar, and boiled over a low fire till it acquired a required consistency that is three Tar, and sugar percentage at this stage was 70%, when tested with the help of refractometer. Afterwards, the powdered ingredient drugs are mixed thoroughly in Qiwam to prepare Majoon. Zafran was grounded in Arq-e-Gulab (rose distillate) in china clay mortar as pestle before mixing in the qiwam. It was added in the last to the previously prepared Majoon and whole mass was made homogenous by stirring(Anonymous, 2007).

Dose of NPM: 6-12 gm

Physico-chemical studies

The Physicochemical studies includes the organoleptic characteristics of NPM, alcohol and water soluble contents, successive extractive values, ash values, moisture content, pH values, specific gravity, viscosity and Qualitative analysis of various constituents present in NPM. Thin Layer Chromatography/TLC studies of the extracts of test drug (NPM) were carried out using different organic solvent systems (Afaqet al., 1994; Jenkins et al., 2008; Anonymous, 1970). Qualitative Analysis of Chemical Constituents: The qualitative analysis of different chemical constituents, present in NPM was carried out.

RESULTS

The organoleptic characteristics of NPM were found to be, the colour of majoon was reddish brown, the appearance was semi-solid, smell was pleasant, the texture was thick and sticky and the taste was found to be sweet. The alcohol and water soluble contents, successive extractive values, ash values, moisture content, pH values, specific gravity, viscosity, qualitative analysis of various constituents present in NPM and thin layer chromatography (TLC) were determined and tabulated (Table 2-5). The physicochemical analysis (Alcohol and water soluble contents, successive extractive values, Total ash, acid insoluble ash, water soluble ash, moisture content, pH values, specific gravity, viscosity) were showed its genunity. All values were found to be statistically significant and within the prescribed limits. The presence of phenols, tannins, sterols/terpens, flavonoids and reducing sugar was revealed by qualitative examination of various extract of NPM. TLC profiling of diethyl ether extract and ethanolic extract of NPM confirms the presence of various bio-molecules in the formulation (Fig. 1-2).

DISCUSSION

The efficacy of a drug mainly depends upon its physical and chemical properties therefore, the determination of physicochemical characters for the authenticity of a drug is necessary before studying it for pharmacological activity. Following parameters were used for the physicochemical study of NPM.

For establishing the standards of any drug the extractive values play an important role, as the adulterated or exhausted drug material will give different values rather than the extractive percentage of the genuine one.

Table 2. Physico-chemical analysis of NPM

S. No.	Physico-chemical Parameters	Mean ± SEM
1.	**Solubility (%)**	
	Alcohol soluble content	11.46±0.44
	Water soluble content	19.47±1.12
2.	**Successive extractive values in different organic solvents (%)**	
	Petroleum ether	0.638±0.025
	Diethyl ether	0.193±0.010
	Chloroform	0.589±0.011
	Alcohol	53.926±2.27
	Distilled water	14.363±1.36
3.	**Ash Value (%)**	
	Total Ash	1.83±0.166
	Acid insoluble Ash	0.66±0.166
	Water soluble Ash	1.3±0.05
4.	**Moisture content (%)**	12.1±0.42
5.	**pH Values**	
	pH of 1% solution	6.30±0.240
	pH of 10% solution	9.28±0.193
6.	**Specific Gravity**	1.282±0.026
7.	**Viscosity of different concentration of NPM**	
	10%	9.630±0.119
	30%	50.136±1.551
	50%	336.458±10.884
	70%	603.833±22.540

Percentage of Solubility is also considered as an index of purity, as alcohol can dissolve almost all substances including glycosides, resins, alkaloids etc. (Jenkins et al., 2008). The ash value determination furnishes a basis of judging the identity and cleanliness of a drug and give information related to its adulteration with inorganic matter (Jenkins et al., 2008). The moisture content of the drug is variable because mostly herbal drugs are hygroscopic and excessive moisture content becomes an ideal medium for the growth of different type of micro-organisms like bacteria and fungi. They subsequently spoil the purity of drug (Zameer, 2013). The Specific gravity of a substance is taken as the ratio of the substance to the weight of an equal volume of distilled water at the same temperature (Jenkins et al., 2008).

Table 3. Qualitative analysis of NPM.

S. No.	TEST FOR	RESULT
1.	Alkaloids	-ve
2.	Amino acids	-ve
3.	Proteins	-ve
4.	Phenols	+ve
5.	Tannins	+ve
6.	Sterols/terpens	+ve
7.	Glycosides	-ve
8.	Flavonoids	+ve
9.	Resins	-ve
10.	Starch	-ve
11.	Reducing sugars	+ve
12.	Non reducing sugars	-ve
13.	Saponins	-ve

Table 4. TLC Profile of diethyl ether extract of NPM

Treatment	Solvent System as petroleum ether: diethyl ether (2:1)	
	No of spots	**Rf value and colour of spots**
Day light	1	0.43 (dark yellow)
UV short	3	0.10 (violet), 0.22(pink), 0.43 (brown)
UV long	0	0
Iodine vapour	2	0.22 (yellow), 0.43 (orange)

Table 5. TLC Profile of ethanolic extract of NPM

Treatment	using solvent system as Toluene : Ethyl acetate(4:1)	
	No of spots	**Rf value and colour of spots**
Day light	2	0.55(dark yellow), 0.70 (yellow)
UV short	3	0.37(violet), 0.55(dark brown), 0.43(brown)

The pH provides a useful practical means for the quantitative indication of the acidity and alkalinity of a solution (Anonymous, 1968). The viscosity of a fluid substance is constant for any given temperature and is measurable characteristic of the substance. The viscosities of solutions and liquid mixtures often vary with their concentration and composition; this property, however, may be used in many cases as a rapid means of analysis (Jenkin et al., 2008). Qualitative phytochemical analysis of the NPM was also carried out for the determination of the presence of alkaloids, flavonoids, glucosides, tannins, phenols, resins, sterols/terpenes, sugars, starch, amino acid, proteins and saponins. The therapeutic properties of the drugs are mainly due to physiologically active chemical constituents present in the drugs, and the lower percentage of chemical constituents may cause lesser therapeutic values. Thin layer chromatography is one of the important parameters used for detecting the adulteration for judging the quality of the drugs. The resolution of different kinds of chemical components are separated by using TLC and calculating the R_f values after detecting the spots in order to standardize the drug for its identity, purity and strength. The exhausted or deteriorated drugs may lose the components and the number of spots appeared might be less. Keeping this in mind TLC studies of different extracts obtained in different organic solvents of the test drug (NPM) have been conducted, and R_f values of various spots appeared in different solvents system have been noted (Zameer, 2013).

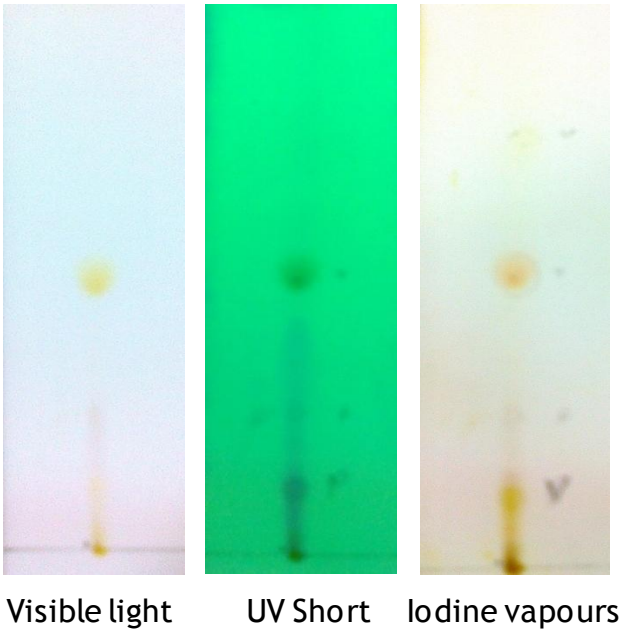

Figure 1. TLC profile of diethyl ether extract of majoon. (Petroleum ether: Diethyl ether = 2:1).

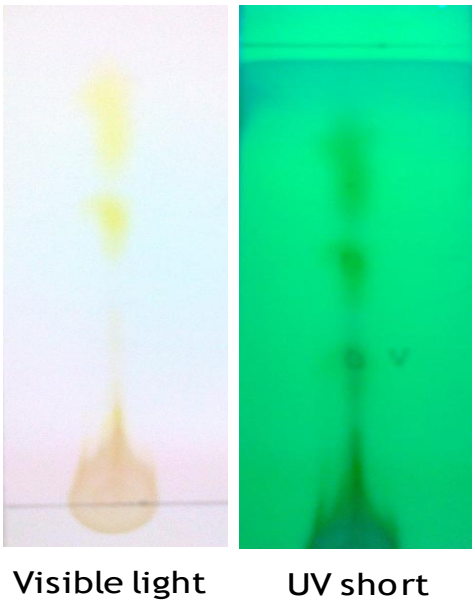

Figure 2. TLC profile of alcoholic extract of majoon (Toulene: Ethyl-acetate = 4:1)

CONCLUSION

Standardization of herbal medicines is very essential for every single/compound formulation in order to obtain and understand uniformity in active principles, therapeutic efficacy and quality of the ingredients. It is very important to establish a system of standardization for every herbal medicine because the scope for variation in different batches of medicine is enormous. Physicochemical constituents present in the drug vary, not only from plant to plant but also among different samples of same species, depending upon various atmospheric factors, drying and storage conditions. A little deviation from the normal in terms of quality and quantity of the constituents may alter the effect of the drug. Apart from the degradation in the quality of the drugs that occurs due to above conditions, adulteration also contributes to variability. The physicochemical studies therefore, on the drug under study, were carried out to standardize the drug sample and to characterize for the future reference.

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CONFLICT OF INTEREST

None declared.

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