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Physico-chemical Standardization of NPCF (Non-Pharmacopoeial Compound Formulation) Use in Diabetes mellitus

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ABSTRACT

Background: Variety of reasons has been cited for the need for scientific evaluation and standardization of herbal drugs. Three methods, viz., activity-based standardization, determination of biologically active compound and standardization of herbal drugs on various physical, chemical and other parameters were found to be suitable and practically applicable. Phytochemical investigations along with biological screening to understand the therapeutic dynamics of medicinal plants etc. will help in developing quality parameters and help in the standardization and establish for authenticity and quality. **Material and methods**: Standardization was made on the basis of physicochemical and analytical parameters laid down by National Unani Pharmacopoeia Committee (Anonymous, 2007). **Results**: The parameters studied includes alcohol soluble content 15.34±0.48 water soluble content 18.27±0.38, successive extractive values viz. petroleum ether 7.60±0.05 , diethyl ether 1.24±0.02, chloroform 2.24± 0.04 , acetone 4.74±0.02, alcohol 8.51±0.06 , and aqueous 4.20±0.05, non- successive extractive values viz. petroleum ether 6.70±0.06, chloroform 7.70±0.06, alcohol16.15± 0.03 and aqueous 10.65±0.03, total ash 5.50±0.28 , acid insoluble ash 2.33±0.33, water soluble ash 1.16±0.16, moisture content 7.30±0.12 , Bulk density 0.419±0.005 (pour density) and 0.74±0.01 (Tap density), pH values of 1% solution 4.89±0.01 and 10% solution 4.69±0.005. The qualitative analysis of various phytochemicals was estimated that revealed the presence of alkaloid, carbohydrate, flavonoids, protein, starch, phenols, tannin, sterols, amino acid and resin. The TLC profile of the extracts of non-pharmacopoeial Compound Formulation was also performed which confirms various biomolecules in it.. **Conclusion**: This study helps in determining the quality and purity of NPCF which is use in Diabetes mellitus.

Keywords: Standardization, Non-Pharmacopoeial Compound formulation, Physico-chemical study

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INTRODUCTION

According to World Health Organization about 65-80% of World's population in developing countries depends essentially on plants for their primary health care[1].

The Unani system of medicine employs a large number of drugs which are of herbal origin. This system of medicine has been given due recognition by the World Health Organization besides many other health agencies. Due to the increasing demand of Unani drugs and consideration of the commercial angle, the quality control of the herbal drugs has become essential[2].

WHO has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable parameters and standards[3].

Despite gaining recognition as relatively safer therapy, adverse effects of herbal products have been reported mainly due to issue of quality. Contamination and adulteration have been reported in many herbal products leading to serious toxicities[4,5].To achieve clinical success, the traditional medicines need to attain high standards of quality, safety and efficacy. Diverse approaches have been tested to evaluate the toxicity potential of chemicals, drugs including traditional medicines[6,7,8] . Recently, several metabolomic studies have been conducted to prove the efficacy and safety, explore the underlying mechanisms, and identify the potential biomarkers to understand the mechanism of action of traditional medicines with useful results especially on traditional Chinese medicine[9,10,11].

MATERIAL AND METHOD

Ingredients of the NPCF 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.

Physico-chemical studies

The Physicochemical studies includes the organoleptic characteristics of NPCF, alcohol and water soluble contents, successive extractive values, ash values, moisture content, ph values and Qualitative analysis of various constituents present in NPCF. Thin Layer Chromatography/TLC studies of the extracts of test drug (NPCF) were carried out using different organic solvent systems[12,13,14]. Qualitative Analysis of Chemical Constituents, present in NPCF was carried out.

RESULTS

The organoleptic characteristics of NPCF were found to be, the colour of Qurs was green, the appearance was solid, taste was bitter, odour was agreeable, texture was hard, weight of the tablet. The alcohol and water soluble contents, successive and non-successive values, ash values, ash values, moisture content, pH values, qualitative analysis of various constituents present in NPCF and thin layer chromatography (TLC) were determined and tabulated. The physicochemical analysis (Alcohol and water soluble content, successive extractive values, Total ash, acid insoluble ash, water soluble ash, moisture content, ph values) 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 other were revealed by qualitative examination of various extract of NPCF. TLC profiling of petroleum ether extract, diethyl ether extract and alcoholic extract of NPCF conforms the presence of various biomolecules in the formulation.

Table 1: Organoleptic Characters of Powder Drugs

S. No.	Parameter	
1.	**Colour**	Green
2.	**Appearance**	Tablet
3.	**Taste**	Bitter
4.	**Odour**	Agreeable
5.	**Texture**	Hard

Table 2: Physico-chemical Parameters

S. No	Parameters	Means± SEM
1	**Weight of the tablet**	631.08±0.005
2	**Thickness**	5.36±0.03
3	**Diameter**	13.23±0.03
4	**Disintegration Time** Distilled Water (minutes) Gastric fluid (minutes)	 3.50±0.23 2.31±0.13
5	**Friability (%)**	0.7±0.05
6	**Solubility (%)** Alcohol soluble Content Water soluble Content	 15.34±0.48 18.27±0.38
7	**Successive extractive Values in different Organic Solvents (%)** Petroleum ether Diethyl ether Chloroform Alcohol Acetone Distilled Water	 7.60±0.05 1.24±0.02 2.24±0.04 8.51±0.06 4.74±0.02 4.20±0.05
8	**Non-successive extractive Values in different Organic Solvents (%)** Petroleum ether Diethyl ether Chloroform Distilled Water	 6.70±0.06 7.70±0.06 16.15±0.03 10.65±0.03
9	**Ash Value (%)** Total ash Acid insoluble Ash Water soluble Ash	 5.5±0.28 2.33±0.33 1.16±0.16
10	**Moisture content (%)**	7.30±0.12
11	**Loss of weight on drying at 105^{0}C (%)**	7.33±0.03
12	**Bulk density (gm/ml)**	0.419±0.005 (Pour density) 0.74±0.01 (Tap density)
13	**pH values** **pH of 1% solution** **pH of 10% solution**	 4.89±0.01 4.69±0.005

Table 3: Qualitative analysis of NPCF

S.No	**Test for**	**Result**
1.	**Alkaloids**	+VE
2.	**Amino acids**	+VE
3.	**Proteins**	+VE
4.	**Phenols**	+VE
5.	**Tannins**	+VE
6.	**Sterols**	+VE
7.	**Glycosides**	+VE
8.	**Flavonoids**	+VE
9.	**Resins**	+VE
10.	**Starch**	+VE
11.	**Carbohydrate**	+VE

Table 4: Fluorescence Analysis of NPCF in different chemical reagent

S. No.	**Powder Drug**	**Daylight**	**UV Short**	**UV Long**
1	P.drug+Conc. NNO_3	Yellow	Green	Black
2	P.drug+Conc. HCl	Yellow	Green	Black
3	P.drug+Conc.H_2SO_4	Dark Brown	Blackish brown	Black
4	P. drug+ 2% Iodine solution	Brown	Dark brown	Black
5	P.drug+Glacial Acetic acid+HNO_3	Orange	Green	Black
6	P.drug+ Glacial Acetic acid	Orange	Green	Black
7	P.drug+NaOH(10%)	Yellow	Green	Brown
8	P.drug+Dil HNO_3	Orange	Green	Black
9	P.drug+Dil H_2SO_4	Brown	Black	Black
10	P.drug+dil HCl	Dark brown	Dark green	Black
11	P.drug+Dragendroff's reagent	Orange	Dark green	Black
12	P.drug+ Wagner's reagent	Greenish yellow	Green	Black
13	P.drug+ Benedict's	Green	Dark green	Black
14	P.drug+ Fehling reagent	Yellow	Green	Black
15	P.drug+ KOH (10%) methanolic	Black	Black	Black
16	P.drug+$CuSO_4$ (5%)	Brown	Dark Green	Black
17	P.drug+ Ninhydrin (2%) in acetone	Light Brown	Green	Black
18	P.drug+Picric acid	Bright yellow	Light green	Black
19	P.drug+Lead Acetate (5%)	Light brown	Green	Black

Table 5: Fluorescence Analysis of the Successive extracts of NPCF

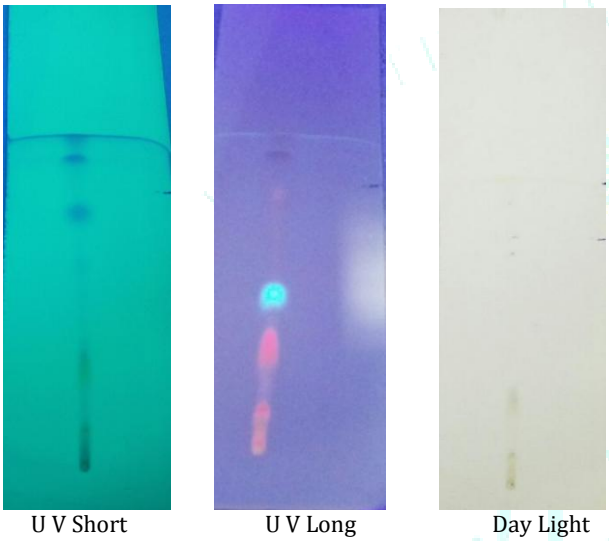
S. No.	**Extract**	**Daylight**	**UV Short**	**UV Long**
1.	**Petroleum ether**	Light brown	Light green	Green
2.	**Diethyl ether**	Light brown	Light green	Black
3.	**Chloroform**	Light green	Light green	Black
4.	**Alcohol**	Dark brown	Black	Black
5.	**Distilled Water**	Dark brown	Greenish black	Black

Table 6: Fluorescence Analysis of the Non-Successive extracts of NPCF

S. No.	**Extract**	**Daylight**	**UV Short**	**UV Long**
1.	**Petroleum ether**	Light brown	Light green	Green
2.	**Chloroform**	Green	Green	Black
3.	**Alcohol**	Dark brown	Black	Brown Black
4.	**Distilled Water**	Dark brown	Greenish black	Black

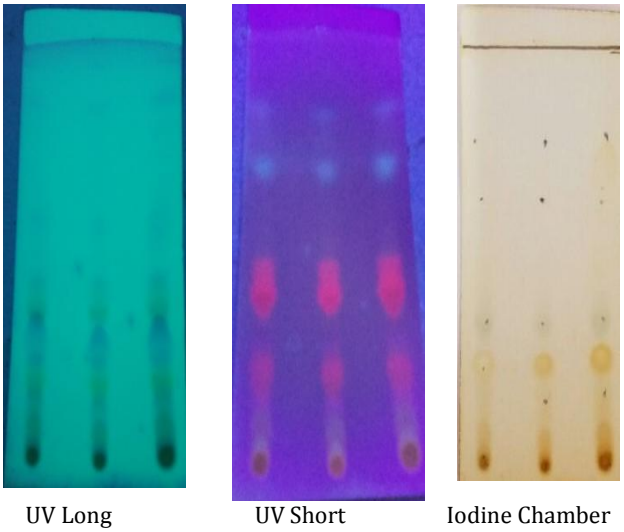
Table7: TLC Profile of Diethyl ether extract of NPCF

Extract	Solvent System	Treatment	No. of spots	R_f Value & colour of spots
Petroleum ether Extract	Chloroform: Benzene (1:4)	Day Light	2	0.107(Black), 0.267(Black)
		UV Short	4	0.107(Reddish Brown), 0.267(Yellowish green), 0.732(Purple), 0.928(Purple)
		UV Long	4	0.089(Pink), 0.267(Red), 0.410(White), 0.875(Blackish Purple)
Diethyl ether Extract	Petroleum ether: diethyl ether (2:1)	U V Short	9	0.062(Light brown), 0.125(Light brown), 0.156(Green), 0.218(Blue), 0.281(Blue), 0.343(Green), 0.406(Blue), 0.562(Blue), 0.75(Blue)
		U V Long	5	0.072 (Light Green), 0.152 (Red), 0.333(Red), 0.611(Blue), .0791(Blue)
		Iodine Chamber	2	0.111(Light Orange), 0.375(Light Orange)
Alcoholic Extract	Toluene: Ethyl acetate (4:1)	Day Light	1	0.771(Light orange)
		U V Short	1	0.785(Yellow)
		UV Long	6	0.128(Red), 0.157(Light Purple), 0.228(White), 0.628(Light Purple), 0.657(White), 0.728(Blue), 0.757(Light Orange), 0.785(Pink)



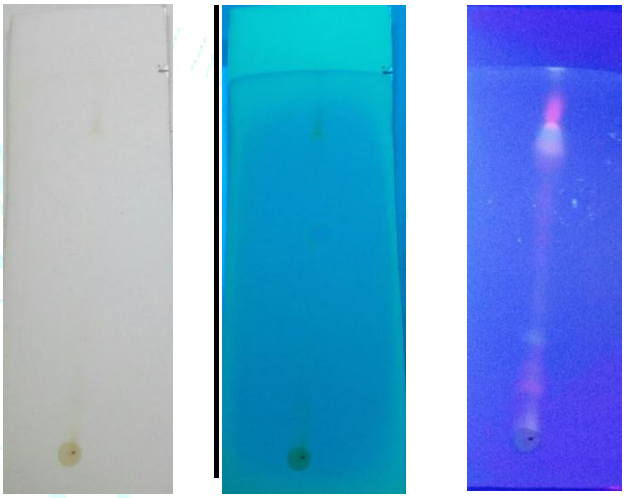
U V Short U V Long Day Light

Figure 1: T.L.C. Profile of Petroleum ether extract of NPC



UV Long UV Short Iodine Chamber

Figure 2: T.L.C. Profile of Diethyl ether NPCF



Day light U V Short U V Long

Figure 3: T.L.C. Profile of Alcoholic extract of NPCF

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/ Clinical study. Following parameters were used for the physicochemical study of NPCF.

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.

CONCLUSION

According to the WHO definition, herbal drugs contain as active ingredients plant part or plant materials in the crude or processed state plus certain excipients, i.e. solvents, diluents or preservatives. The active principles responsible for their pharmacological actions are not usually known.

Standardization can help to maximize compatibility, interoperability safety, repeatability, or quality. It can also facilitate commoditization of formerly custom processes. 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.

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 drugs. 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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