Quality Standards of *Safoof-e-Barangi*: A Unani Polyherbal Powder Formulation

[1]Mohd Ikram,
[*2]Hamiduddin,
[1]Mohd Zaigham,
[1]Gazi Jahangeer Rather and [3]Roohi Zaman

[1]P.G. Scholar,
[2]Lecturer,
[3]Reader and
Head of the Department of Ilmul Saidla, National Institute of Unani Medicine, Bangalore

Abstract

Safoof-e-Barangi (SB) is a Unani polyherbal powder formulation used to treat *Deedan-e-Ama* (intestinal worm) since a long time. The objective of the study is to establish the standardization of SB by using scientific analytical procedures. In this study SB is evaluated for its various organoleptic and physico-chemical parameters. SB is buckthorn brown, odorless and bitter in taste. The physico-chemical parameters are expressed as mean values of the loss of weight on drying, total ash, acid insoluble ash and water soluble ash as 4.82± 0.18, 4.05 ± 0.24, 2.80 ± 0.14 and 1.30±0.06 respectively. The mean values of bulk density, tapped density, angle of repose, Hausner's ratio and compressibility index were 0.5481 ± 0.0042, 0.6922 ± 0.0026, 35.47± 1.02°, 1.278 ± 0.022º and 20.7887 ± 0.6785 respectively, pH of 1% and 10% solution were 4.9 ± 0.1 and 5.5 ± 0.1 respectively. Extractive values in petroleum ether, benzene and ethyl alcohol by successive extraction method were 2.07 ± 0.13, 1.02 ± 0.04 and 12.86 ± 0.35 respectively. Extractive values in petroleum ether, benzene and ethyl alcohol by non-successive extraction method were 2.07 ± 0.13, 2.40 ± 0.30, and 13.18 ± 0.35 respectively. Qualitative analysis showed the presence of all major organic constituents except proteins, saponins and steroids.

Keywords: *Deedan-e-Ama*, Intestinal worm, Quality standard, *Safoof-e-Barangi*

Introduction

Herbal drugs are gaining popularity in the world since last decade because of its efficacy and lower toxicity as compared to allopathic drugs. The use of herbs and their formulations to treat diseases has stood the test since ancient time. The chemical constituents present in herbal medicine are a part of the physiological functions of living flora and hence they are believed to have better acceptance within the human body (Afaq et al., 2012). With this growing need for use of safe drug more attention is drawn for quality of these formulations. Mixture of exhausted drugs is one of the major problems which has to be tackled (Kumar et al., 2011). Now, herbal medicines are manufactured on a large scale basis in mechanical units where manufacturers come across many problems such as non-availability of Standard Operational Procedure (SOP), proper methodology for standardization, non-availability of good quality raw materials etc (Afaq et al., 2012).

SB is a polyherbal powder formulation used in the Unani System of Medicine for treatment of Deedan-e-Ama (intestinal worm). This formulation also contains Halela Kabuli (*Terminalia chebula* (*Gaertn*) *Retz.)*, Aamla (*Emblica officinalis* Gaertn.), Baobarang (*Embelia ribes* Burm *f.*), Turbud Safaid (*Operculina turpethum* (L.) S. Manso), Faneez (Batasha / processed sugar) (Anonymous, 2006). As per the review of literature, so far this formulation has not been evaluated for its physico-chemical standardization and microbiological characterization. Thus, keeping this view in mind, the present study was carried out to fix the quality control standards of SB with scientific analytical techniques.

* Author for Correspondence; Email: drhamid2003@rediffmail.com

Methodology

Procurement of Raw Drugs

Ingredients of *Safoof-e-Barangi* were procured from the herbal / raw drug dealer at Bangalore, Karnataka, India. The identification of these drugs was done by the experts at National Institute of Unani Medicine, Kottigepalya, Bangalore. Detail of ingredients is presented in Table 1.

Table 1: Ingredients of *Safoof-e-Barangi*

S. N.	Drug name	Botanical name	Part used	Proportion
1.	Halela kabuli	*Terminalia chebula*	Fruit	5.55%
2.	Aamla	*Emblica officinalis*	Fruit	5.55%
3.	Baobarang	*Embelia ribes Burm f*	Seed	5.55%
4.	Turbud safaid	*Operculina turpethum*	Rhizome	16.6%
5.	Faneez (Batasha) Sugar	----------	Crystals	66.6 %

Preparation of Formulation

All the drugs were first cleaned, dried in shade and powdered by passing through sieve no. 80. The formulation was prepared as per the method described in National Formulary of Unani Medicines. Figure 1 (Anonymous, 2006, NFUM Part IV).

Fig. 1: Safoof-e-Barangi

Physico-chemical Evaluation

The formulation was evaluated for organoleptic characters *i.e.* color, odor, taste (Anonymous, 2006); bulk and tapped density, Hausner's ratio, compressibility index (Anonymous, 2012) (Ali et. al. 2016) loss of weight on drying, total ash, acid insoluble ash, water soluble ash, alcohol soluble and water soluble matter (extractives), pH of 1% and 10% as per the method mentioned in UPI (Anonymous, 2010).

Successive Extractive Value and Non-Successive Extractive Value

Successive Extractive Value

The coarse powder of SB was extracted successively using Soxhlet apparatus with different solvents in increasing order of polarity viz; petroleum ether → benzene → chloroform → ethanol. 10 g powdered drug was taken and subjected to successive extraction with each solvent for 6 hours. After that the extracts were filtered first by using filter paper (Whatman No. 1) and dried on water bath. The extractive values were determined with reference to the weight of the drug taken (w/w). The procedure was repeated three times to calculate mean extractive values.

Non Successive Extractive Value

The coarse powder of SB was extracted separately in different solvents (water, ethyl alcohol and petroleum ether) using soxhlet apparatus. 10 g powdered drug was taken and subjected to separate extraction with each solvent. The extracts were filtered first by using filter paper (Whatman No. 1) and evaporated on water bath. Extractive values were determined with reference to drug taken (w/w) (Ali et al., 2016).

Qualitative Estimation

Qualitative estimation for organic constituent's viz. alkaloid, glycosides, tannins, flavanoids, carbohydrates, saponins, phenols, proteins, resin, starch and steroids was done (Anonymous, 2006).

HPTLC Fingerprinting Analysis

The weighed quantity (10g) of SB was extracted in a Soxhelt apparatus for 6 hours using 200 ml of solvent (ethanol) at a controlled temperature. HPTLC was performed on 20 cm × 10 cm aluminum backed plates coated with silica gel 60F254 (Merck, Mumbai, India). Standard solution of sample was applied to the plates as bands by use of a Camag (Muttenz, Switzerland) Linomat V sample applicator equipped with a 100 µl Hamilton (USA) syringe. Ascending development to a distance of 80 mm was performed at room temperature (28 ± 2°C) with toluene: ethyl acetate, formic acid 5 : 4 : 1 (v/v), as mobile phase, in a Camag glass twin-trough chamber previously saturated with mobile phase vapour for 20 min. After development, the plates were dried and then scanned at 254 nm and 430 nm with a Camag TLC Scanner with WINCAT software, using the deuterium lamp (Devies, 1990).

Results

Powder characterization of Safoof-e Barangi, physico-chemical evaluation of samples of Safoof-e- Barangi, successive extraction and non-successive extraction and phytochemical screening of *Safoof-e-Barangi* are given in Table 2, Table 3, Table 4 and Table 5.

Table 2: Powder Characterization of *Safoof-e-Barangi*

Parameters	Bulk density (gm/ml)	Tapped density (gm/ml)	Car's index	Hausner's Ratio	Angle of Repose
Mean± SEM	0.5481 ± 0.0042	0.6922 ± 0.0026	20.7887± 0.6785	1.278 ± 0.022	35.47± 1.02

Table 3: Physico-chemical Evaluation of *Safoof-e-Barangi*

Parameters	Total ash (%w/w)	Acid insoluble ash (%w/w)	Water soluble ash (%w/w)	Alcohol soluble matter (%w/w)	water soluble matter (%w/w)	Loss on drying (%w/w)	pH 1 % solution (%w/v)	pH 10 % solution (%w/v)
Mean ± SEM	4.05 ± 0.24	2.80 ± 0.14	1.30 ± 0.06	9.96 ± 0.22	65.86 ± 1.07	4.82 ± 0.18	4.9 ± 0.1	5.5 ± 0.1

Table 4: Successive Extraction and Non-Successive Extraction

Successive extractive value (%w/w)				Non-Successive extractive value (%w/w)		
Mean ± SEM	Petroleum ether	Benzene	Ethanol	Petroleum ether	Benzene	Ethanol
	2.07 ± 0.13	1.02 ± 0.04	12.86 ± 0.35	2.07 ± 0.13	2.40 ± 0.30	13.18 ± 0.35

Table 5: Phyto-chemical Screening of *Safoof-e- Barangi*

Parameters	Result
Alkaloids	+
Glycosides	+
Tannins	+
Flavanoids	+
Carbohydrates	+
Phenols	+
Proteins	-
Saponins	-
Resin	+
Starch	+
Steroids	-

HPTLC Fingerprinting Analysis

HPTLC analysis in Solvent (Toluene: Ethyl acetate: Formic acid 5:4:1) was done. Densitometric Scan of *Safoof-e Barangi* at 254 nm Wavelength and *Rf* value, No. of Peaks, peak area and height of *SB* at 254 nm are depicted in Figure 2 and Figure 3. HPTLC Densitometric Scan of *Safoof-e-Barangi* at 430 nm Wavelength and *Rf* value, number of Peaks, peak area and height of *SB* at 430 nm are depicted in Figure 4 and Figure 5 respectively. TLC images of ethanol extract at UV - 254 nm and 366 nm. are depicted in Figure 6. HPTLC fingerprint profile of ethanolic extract of SB at 254 nm and 430nm is depicted in Figure 7.

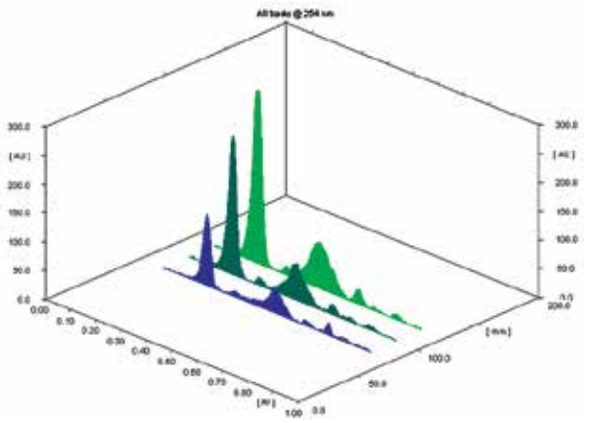
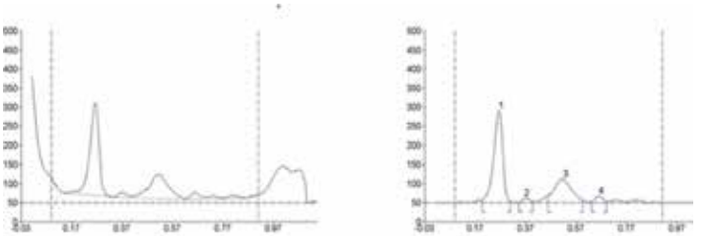


Fig. 2: HPTLC Densitometric Scan of Safoof-e Barangi at 254 nm Wavelength



Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %	Assigned substance
1	0.20	6.9	0.27	241.0	71.69	0.31	4.1	6936.1	62.03	unknown *
2	0.35	0.8	0.37	12.6	3.75	0.40	2.2	295.9	2.65	unknown *
3	0.46	18.4	0.52	63.7	18.94	0.60	6.0	3484.6	31.16	unknown *
4	0.63	3.4	0.66	18.9	5.63	0.69	3.6	464.6	4.16	unknown *

Fig. 3: Rf value, No. of Peaks, peak area and height of SB at 254nm

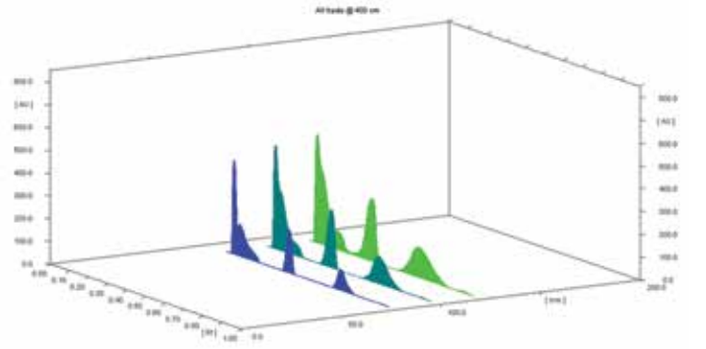
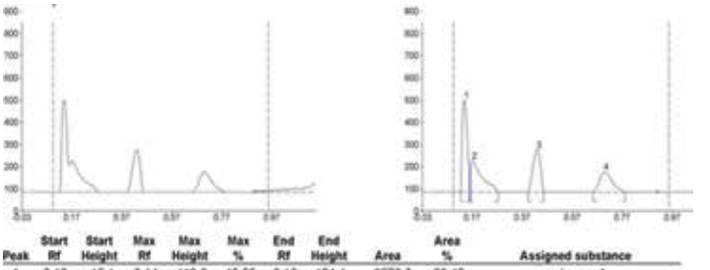
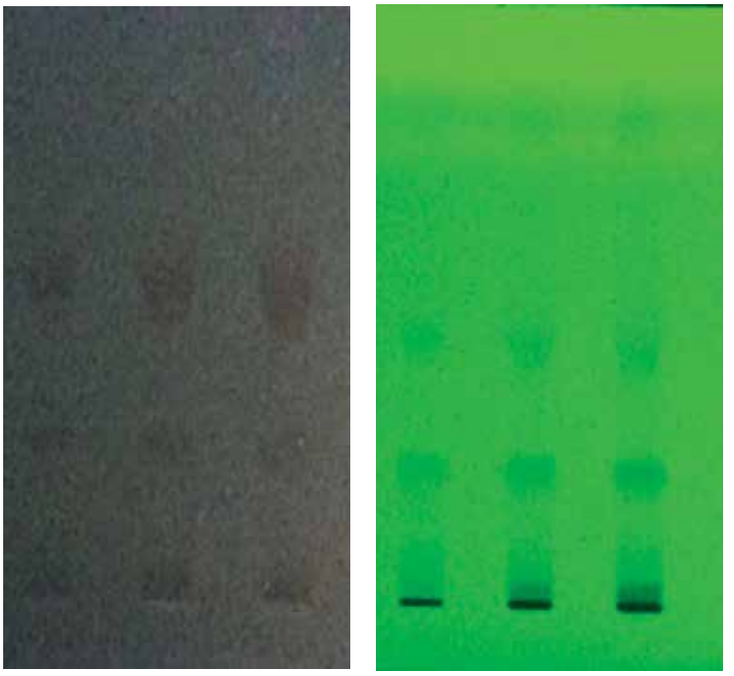


Fig. 4: HPTLC Densitometric Scan of Safoof-e-Barangi at 430 nm Wavelength



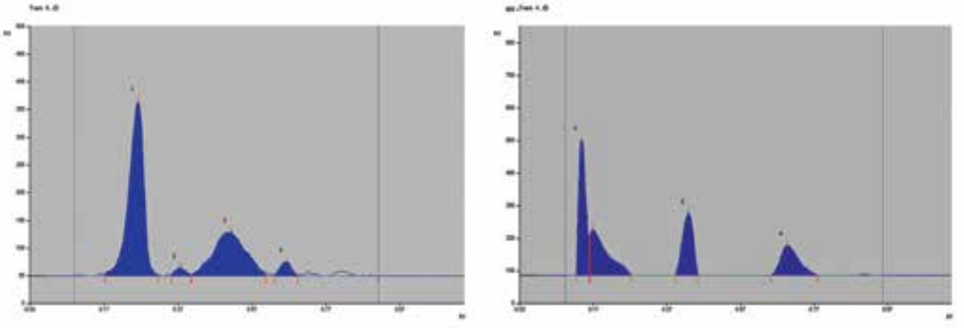
Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %	Assigned substance
1	0.13	15.1	0.14	413.6	49.53	0.16	121.1	6579.8	33.12	unknown *
2	0.16	122.4	0.17	140.1	16.78	0.28	1.0	5225.2	26.30	unknown *
3	0.39	1.2	0.43	190.0	22.75	0.46	1.4	4458.8	22.44	unknown *
4	0.65	0.0	0.70	91.4	10.94	0.78	0.0	3603.9	18.14	unknown *

Fig. 5: Rf value, No. of Peaks, peak area and height of SB at 430 nm



254 nm 366nm

Fig. 6: TLC photos of ethanol extract at UV - 254 nm and 366 nm



254 nm 366nm

Fig. 7: HPTLC fingerprint profile of ethanolic extract of Safoof-e-Barangi at 254 nm and 430nm L to R

Discussion

Finished product of *Safoof-e-Barangi* was buckthorn brown as per colour chart (No. 18-0935 TPX of Panton color chart), bitter in taste, odorless and without any clumping and aggregation. The mean values of bulk density, tapped density, angle of repose, Hausner's ratio and compressibility index were 0.5481 ± 0.0042, 0.6922 ± 0.0026, 35.47º ± 1.02, 1.278 ± 0.022 and 20.7887± 0.6785 respectively.

Hausner's ratio and compressibility index are the simple and popular method to determine the flow characteristics of powder. The flow characteristics of powder depend on the size, shape, size distribution of particles and moisture content. Increase in the moisture content of a powder results in decreasing the ability

to flow smoothly due to the increased thickness of adsorbed liquid layer that enhances the strength of liquid bridges formed between particles.

Finished *Safoof-e-Barangi* has Hausner's ratio of 1.25 to 1.5, it indicates good / moderate flow-ability (Manjula et al., 2012). The compressibility index of SB lies between 21 and 25 according to the scale of flowbility. Test drug SB has a fair passable flow character (Anonymous, 2009 USP). Angle of repose displayed passable flow property (Manjula et al., 2012) (Table 2)

The mean percentage of loss of weight on drying of SB was 4.82± 0.18 (Table 3). It is mentioned that the water content in plant drugs can vary between 8% and 14%. The presence of excessive amount of moisture in plant drugs causes hydrolysis of constituents, growth of bacteria and fungi and biochemical reactions. The pharmacopoeial monographs compulsorily limit the water content, especially in drugs that have hygroscopic nature or in which the excessive amount of water causes deterioration of products (Aulton, 2009, Junior et al., 2011). As finished SB contains very less amount of moisture it can be expected that it will be safe for a long time. Total ash value was 4.05 ± 0.24, acid insoluble ash was 2.80 ± 0.14 and water soluble ash was 1.30±0.06 displaying less inorganic content (Table 3). pH of *Safoof-e-Barangi* in 1% solution was 4.9 ± 0.1 while the pH of 10% solution was 5.5 ± 0.1 (Table 3). It is slightly acidic in nature. In a study by Abba et al., (2008) correlated the pH with microbial contamination and they suggested that a neutral or alkaline pH favours high microbial contamination levels of the herbal preparations.

Extractive values in petroleum ether, benzene and ethylalcohol by successive extraction method were 2.07 ± 0.13, 1.02 ± 0.04 and 12.86 ± 0.35 respectively. Extractive values in petroleum ether, benzene and ethyl alcohol by non-successive extraction method were 2.07 ± 0.13, 2.40 ± 0.30 and 13.18 ± 0.35 respectively. (Table 4)

Extractive value of a drug in defnite solvent is an index of purity of a drug and plays a major role to determine adulteration also. Amount of the extract of a drug in a particular solvent is often an appropriate measure of the amount of a certain constituent that drug contains. The amount of drug soluble in a particular solvent is an index of its purity (Tauheed et al., 2017).

Organic constituents viz. alkaloid, glycosides, tannins, flavanoids, carbohydrates, saponins, phenols, proteins, resin, starch and steroids were qualitatively estimated. Only protein, saponins and steroids were found absent (Table 5).

HPTLC

HPTLC plates of SB were examined. *Rf* value, number of peaks, peak area and peak height were also analysed under 254nm and 430nm (Figure 3 & Figure 5).

Area percentage of peak no. 1 analysed under 254nm was highest and also Area percentage of peak no. 1 in 430nm was highest. Further studies can also be done with the help of standards and quantitative estimation and identification of the ingredients. HPTLC fingerprinting data of this study can help in authentication

and identification of SB in the performed solvent system and extract.

Safoof ingredient such as *Terminala chebula* contains many important constituents like anthraquinones, tannins, sennoside A, polyphenolic compounds, glycosides; *Embelic officinalis* contains Ascorbic acid, gallo tannins; *Embelia ribes* Burm f contains benzoquinones, alkaloids (christembine), tannins; (Anonymous, 2007) and *Operculina turpethum* contains resinous glycosides. (Anonymous, 2008).

Pharmacological activity reported in *Terminala chebula* are ovicidal and larvicidal (in-vitro) (Kamaraj et al., 2011) and wound healing (Choudhary, 2011). In *Emblica officinalis* are antiulcerogenic (Mehrotra et al., 2011), Larvicidal and mosquitocidal activity (Jeyasankar et al., 2012). In *Embelia ribes* Burm f are anthelmintic (Jalalpure et al., 2007) and wound healing activity (Kumara Swamy et al., 2012). In *Operculina turpethum* are anti-ulcer activity (Mahurkar et al., 2012) etc. Reported pharmacological activity and constituent of the ingredients of SB highlight the importance of the study formulation owing to its indications in Unani Medicine.

At present this powder dosage form of SB doesn't have any Pharmacopoeial standards. Various methods and parameters for the assessment of powder dosage form are mentioned in different guidelines and it is necessary to follow them so that these data could be used to set the standards for the formulation and could be taken as standard for quality control purpose to achieve maximum efficacy and safety of medicine.

Conclusion

In this present study, SB was evaluated physico-chemically to set its standards in accordance with contemporary guidelines. This work may be used as standard monograph for identification and further evaluation or future research work on standardization of this formulation.

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सारांश

सफूफ़-ए-बरंगी का गुणवत्ता मानक : एक यूनानी पॉलीहर्बल पाउडर मिश्रण

[1]मो. इकरम, [2*]हमीदुद्दीन, [1]मो. ज़ैग़म, [1]गाज़ी जहांगीर राथर और [3]रूही ज़मां

सफूफ़–ए–बरंगी एक यूनानी पॉलीहर्बल पाउडर मिश्रण है जो लंबे समय से दीदान–ए–अमा (पेट के कीड़े) का उपचार करने के लिए प्रयोग किया जाता है। इस अध्ययन का उद्देश्य वैज्ञानिक विश्लेषणात्मक प्रक्रियाओं का उपयोग करके सफूफ़–ए–बरंगी के मानकीकरण को स्थापित करना है। इस अध्ययन में सफूफ़–ए–बरंगी का मूल्यांकन विभिन्न ऑर्गेनोलिप्टिक और भौतिक–रासायनिक मानकों के लिए किया जाता है। सफूफ़–ए–बरंगी रंग में भूरी, गंध रहित और स्वाद में कड़वी होती है। भौतिक–रासायनिक मानक जैसे कि सुखने पर कम होना, कुल राख, एसिड राख, एसिड में अघुलनशील राख, और जल में घुलनशील राख को क्रमशः 4.82± 0.18, 4.05 ± 0.24, 2.80 ± 0.14 और 4.06 ± 0.18 के औसत मूल्य के रूप में व्यक्त किया जाता है। स्थूल घनत्व, दबाब घनत्व, एंगल ऑफ रिपोस, हॉसनर्स अनुपात और दबाव सूचकांक का औसत मूल्य क्रमशः 0.5481 ± 0.0042, 0.6922 ± 0.0026, 35.47 ± 1.02, 1.278 ± 0.022 और 20.7887 ± 0.6785 पाया गया एवं 1% और 10% विलयन का पीएच क्रमशः 4.9 ± 0.1 और 5.5 ± 0.1 देखा गया। क्रमिक निष्कर्षण विधि द्वारा पेट्रोलियम इथर, बेंज़ीन और इथाईल एल्कोहल के निष्कर्षण मूल्य क्रमशः 2.07 ± 0.13, 1.02 ± 0.04 और 12.86 ± 0.35 मिले। अकर्मिक विधि द्वारा पेट्रोलियम इथर, बेंज़ीन और इथाईल एल्कोहल में निष्कर्षण मूल्य क्रमशः 2.07 ± 0.13, 2.40 ± 0.30 और 13.18 ± 0.35 देखे गये। गुणात्मक विश्लेषण अध्ययन में प्रोटीन, सेपोनिन्स और स्टीरोइड्स को छोड़कर सभी पादपीय रसायन घटक देखे गए।

शब्द कुंजीः दीदान–ए–अमा, पेट के कीड़े, गुणवत्ता मानक, सफूफ–ए–बरंगी