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PREPARATION AND STANDARDIZATION OF 'ITRIFAL SANAIE' -AN UNANI FORMULATION

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ABSTRACT
Itrifal Sanaie is a Unani formulation used for the treatment of constipation. The ingredients of this are *Terminalia chebula, T. bellerica, Emblica officinalis, Cassia angustifolia*, ghee and honey. The formulation was prepared in triplicate as per the procedure mentioned in Bayaz-e-Kabeer, a standard book for the preparation of Unani formulations. The drug powders collected have been checked and confirmed for individual standards prior to the preparation. The formulation was evaluated for organoleptic characters, total ash, acid insoluble ash, alcohol extractive value, water extractive value, total tannins, gallic acid content and fingerprinting of sennosides.

Keywords: *Gallic acid, Sennosides, HPTLC and Fingerprinting*

INTRODUCTION
Itrifal Sanaie is a semisolid Unani formulation used for the treatment of constipation[1]. The present attempt to standardize the formulation has been done by taking into consideration the fact that the formulation has not been standardized so far. All the drug powders have been collected from NKCA pharmacy Ltd., Mysore. The ingredients of the formulation are *Terminalia chebula (Halela), T. bellerica (Balela), Emblica officinalis (Amla khushq), Cassia angustifolia (Sonamukhi/ senna)*, ghee and honey. In case of *halela, balela and amla* dried fruit powder was taken where as leaf powder of *senna* was used to prepare the formulation. The main active principles in the formulation are Tannins and Sennosides responsible for laxative and purgative activity.

MATERIALS AND METHODS
The quantities of ingredients used in the preparation of the formulation are *Terminalia chebula* (20 g), *T. bellerica* (20 g), *Amla* (20 g), *Senna* (20 g), Honey (233 g) and Ghee (20 g). The drug powders were sieved through # 120 and then evaluated for total ash, acid insoluble ash, alcohol extractive value, water extractive value and tannin content as per the procedure mentioned in Ayurvedic Pharmacopoeia of India[2, 3].
After confirming the standards of individual powders, the formulation was prepared as per the procedure mentioned in Bayaz-e-Kabeer, the standard book for the preparation of Unani formulations[1]. Initially *T. chebula and T. bellerica* were mixed with ghee. Later all the remaining drug powders were added and mixed thoroughly for uniform distribution of powders. Honey was added little by little while the drug powders were being mixed until a semisolid formulation was obtained. Then it was evaluated for organoleptic characters, total ash, acid insoluble ash, alcohol extractive value, water extractive value, total tannins, gallic acid content and identification of sennosides which was done by HPTLC fingerprinting[4-8]. All the tests have been done in triplicate.

Estimation of tannin content [9]
It was done by spectrophotometric method. The sample extracts were obtained from methanol: water (6:4) to get both alcohol soluble and water soluble tannins[4]. The known weight of the extract was taken in a 10 ml volumetric flask to which 1ml of 10 fold diluted Folin ciocalteau reagent and 2 ml of 7.5% sodium carbonate solution were added. The volume was made to 10 ml and the absorbance was measured at 765 nm in Schimadzu UV spectrophotometer (UV-1702). Tannins were determined as tannic acid equivalents. A calibration curve of tannic acid was taken by the same method and the amount of tannins in the formulation was determined.

Estimation of Gallic acid [10]
Gallic acid was quantitatively estimated by HPTLC method using Linomat IV automatic sample applicator, Camag TLC scanner 3 and CATS 4 software for interpretation of the data.
Standard solution: 10 mg gallic acid in 10 ml methanol.
Sample solution: 100 mg of formulation in 10 ml methanol.
10 µl of both sample and standard solutions were applied on precoated HPTLC silica gel plates. The plates were developed in the solvent system of toluene: acetone: formic acid (7:5:1) and estimated densitometrically by scanning at a wavelength of 254 nm.

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Fingerprinting of sennosides:
It was done by HPTLC method.
Reference solution: Sennosides extract in 10 ml methanol
Sample solution: 100 mg of formulation in 10 ml methanol
10 µl of both reference and sample solutions were applied on precoated HPTLC silica gel plates. The plates were developed in a solvent mixture of n-propanol: ethyl acetate: water: glacial acetic acid (40:40:29:1) and scanned at 254 nm.

RESULTS AND DISCUSSION

The results obtained for various tests carried on individual powders are shown in Table 1. The results obtained were compared with standards stated in Ayurvedic Pharmacopoeia of India. The results obtained for tests carried on individual powders were well within the standards.

Table 1: *Evaluation data for individual powders*

Tests	*T.chebula*		*T.bellerica*		*Amla*		*Senna*	
	Obt.	Std.	Obt	Std.	Obt	Std.	Obt.	Std.
Total ash	4.67± 0.36%	NMT 5%	5.13± 0.2%	NMT 7%	5.56± 0.55	NMT 7%	10.39± 0.57%	NMT 14%
Acid insoluble ash	2.7 ± 0.22%	NMT 5%	0.91± 0.05%	NMT 1%	1.78± 0.08%	NMT 2%	1.83± 0.07%	NMT 2%
Alcohol extractive Value	50.56± 0.75%	NLT 40%	8.68± 0.54%	NLT 8%	47.30± 0.63%	NLT 40%	7.88± 0.29%	NLT 3%
Water extractive Value	63.6± 0.62%	NLT 60%	37.46± 0.6%	NLT 35%	52.6± 0.65%	NLT 50%	26.65± 0.6%	NLT 25%
Tannins content	26.43± 0.77%	20 to 40%	20.86± 0.76%	20 to 30%	6.49± 0.46%	5 to 10%	NA	NA

The results obtained for various tests carried on formulation are shown in Table 2. The HPTLC chromatograms obtained for Gallic acid and fingerprinting of Sennosides are shown in Figures 1, 2, 3 and 4 respectively. The Rf value of the formulation was found to match with that of marker compound (0.36) and the amount of gallic acid present in the formulation was found to be 0.171±0.15%. The Rf value of the formulation also matched with that of senna leaf extract (0.37). As the evaluation results of the formulation well matched with raw materials, we can conclude that there is no degradation or incompatibility of the drugs in the final formulation.
The data generated from the present study would help in the authentication and evaluation of marketed formulation. The total tannin content, total gallic acid content and fingerprinting of sennosides will be useful in standardization of formulation.

Table 2: *Evaluation data for the prepared formulation*

Parameter	Results
Total ash	1.5±0.03%
Acid insoluble ash	0.816±0.03%
Alcohol extractive value	57.26±0.65%
Water extractive value	57.61±0.52%
Reducing sugars	46.8±0.87%
Total tannins	3.68±0.16%
Gallic acid content	0.171±0.15%

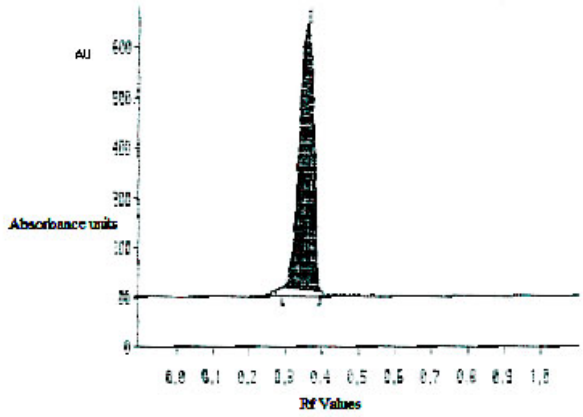

Fig. 1: *HPTLC chromatogram of standard gallic acid*

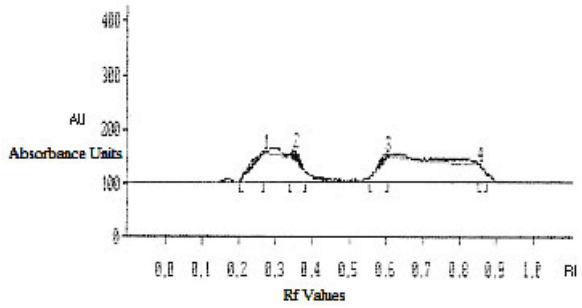

Fig. 2: *HPTLC chromatogram of formulation for gallic acid*

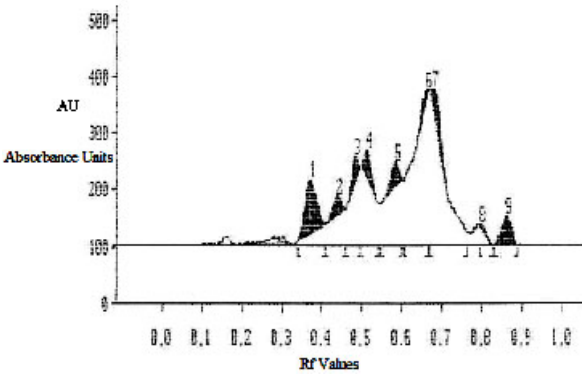

Fig. 3: *HPTLC chromatogram of Sennosides extract*

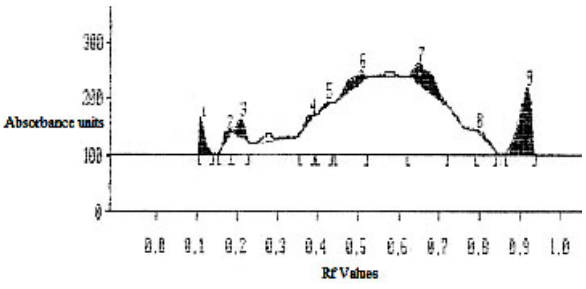

Fig. 4: *HPTLC chromatogram of formulation for Sennosides*

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