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Research Article

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Formulation, evaluation and stability study of sennoside A & B capsule

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ABSTRACT

The objective of research work was to evaluate and perform stability study of prepared and developed Sennoside A and B capsule. The Sennoside A and B capsule was successfully develop by adding optimum necessary active ingredient and all the prepared formulations were evaluated by different methods such as HPLC and dissolution study Moreover, stability study was performed as per ICH guidelines. All five formulations were identified by chromatogram of HPLC as well as performing dissolution and disintegration study. In addition to, organoleptic qualitative and quantitative evaluation of calcium sennoside was carried by consideration of its pH, loss on drying, tapped density, ash value and its assay. The results obtained in this research work clearly indicated that out of all five formulation, formulation IV significantly increased the frequency and wet weight of stools to 31.5 ± 4.25 and 8.29 ± 1.21 g, and showed tendency to increase the frequency and wet weight of stools. The frequency and the wet weight of stools following gum arabic for 14 days were 16.3±3.98 and 4.79±1.14 g respectively.

Key words: Sennoside capsule, Formulation, ICH, Stability study

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INTRODUCTION

In today's busy and fast world, If people ill they swallow fast recovering allopathic medicine which may bear some side effects on their health [1,2]. Now a days people move towards herbal medicine due to toxic and side effect of allopathic medicine [3]. World Health Organization (WHO) has defined herbal medicines as finished labelled medicinal product that contain active ingredients, aerial or underground parts of the plant or other plant material or combinations[4]. Senna is a well-known drug in ayurvedic system of medicine which has been included in most of the pharmacopoeia of the world [5]. In India, this drug is known as Tinnevelly Senna which belongs to Leguminoseae family. Sennoside A and B are of medicinal interest due to their strong laxative properties especially suitable in habitual constipation [6-7].The glycosides are absorbed from the intestinal tract and the active anthraquinones are excreted into the colon where they stimulate and increase the peristaltic movements of the colon and produce a bulky softer fecal mass [8-9].Senna is an FDA-approved non-prescription laxative [10].

EXPERIMENTAL SECTION

Materials

Karaya gum, Croscarmellose Sodium and Methyl Paraben were purchased from Sigma Aldrich, Vadodara, India.

Formulation development: The following ingredients are required to develop the formulation of Sennoside capsule

Table: 1 Development of Sennoside Capsules

Formulation	1st	2nd	3rd	4th	5th
Calcium Sennoside (20%)	66.79	66.79	66.79	66.79	66.79
Karaya gum	-	-	-	500.00	500.00
Starch 1500	145.00	145.00	145.00	100.00	100.00
Croscarmellose Sodium	18.00	23.00	13.00	126.00	106.00
MCC pH102	24.71	19.71	29.71	32.00	52.00
Methyl Paraben	0.20	0.20	0.20	0.20	0.20
Aerosil 200	3.00	3.00	3.00	8.00	8.00
Magnesium Streate	2.30	2.30	2.30	7.00	7.00

Fig.1: Sennoside capsules

RESULTS

Table: 2 Organoleptic and Qualitative / Quantitative evaluations of calcium sennosides 20%

S. No.	Parameters	Observation
1	Appearance	Dark brown amorphous powder
2	Identification: Test for calcium	White precipitate
3	pH	7.95
4	Loss on drying (%w/w)	1.23%
5	Ash Content	14.35%
6	Tapped Density	0.65 g/ml
7	Particle Size (by Sieve)	90% passed through 80 Mesh.
8	Assay	20.45% w/w

Table: 3 Result of all formulation

Formulation	I	II	III	IV	V
Description	Brown colour powder filled in pink colour hard gelatin capsule.				
Identification	**By HPLC:** The retention time of the major peak obtained in the chromatogram of the sample correspond to that obtained in the chromatogram of the Standard preparation.				
Average fill weight of capsule content (mg)	260.45	260.33	260.59	840.49	840.13
Uniformity of dosage unit (By weight variation)	-1.7% + 1.4%	-1.9% + 2.1%	-1.3% + 1.1%	-2.2% + 1.9%	-1.6% + 2.7%
Disintegration Test (minute)	2	1	2	3	4
Assay	100.07%	100.32%	100.18%	100.73%	100.45%
Microbial Parameter	Complied				
In *vitro* evaluation *(*Dissolution*)*	96.78%	97.14%	95.99%	96.06%	94.05%
In *vivo* evaluation	Sennosides and gum karaya capsule better result than sennoside capsule. (Formulation IV was better.)				

Table: 4 Stability study after 3 month at 40º C/75%RH

Formulation	I	II	III	IV	V
Description	Brown colour powder filled in pink colour hard gelatin capsule.				
Identification	**By HPLC:** The retention time of the major peak obtained in the chromatogram of the sample preparation correspond to that obtained in the chromatogram of the Standard preparation.				
Average fill weight of capsule content (mg)	260.89	260.19	260.42	840.26	840.77
Uniformity of dosage unit (By weight variation)	-2.5% + 1.9%	-2.4% + 2.9%	-3.1% + 2.3%	-2.0% + 1.4%	-1.9% + 2.2%
Disintegration Test (minute)	3	2	3	4	4
Assay	99.29%	99.32%	99.18%	99.21%	99.02%
Microbial Parameter	Complied				
In *vitro* evaluation (Dissolution)	94.36%	95.25%	93.23%	92.09%	91.99%

Fig.2: HPLC Graph of Standard

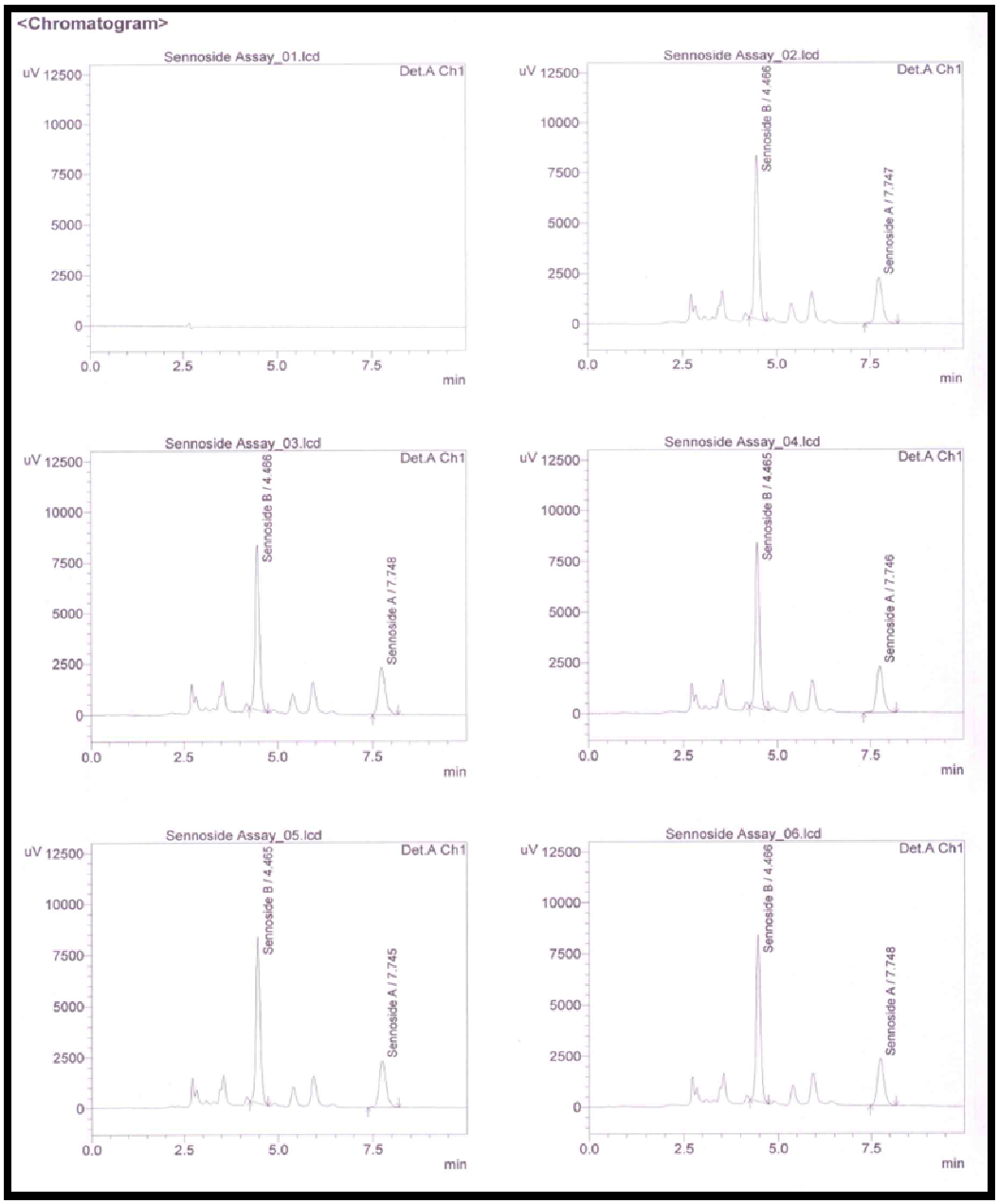


Fig.3: HPLC Graph of Formulation I to III

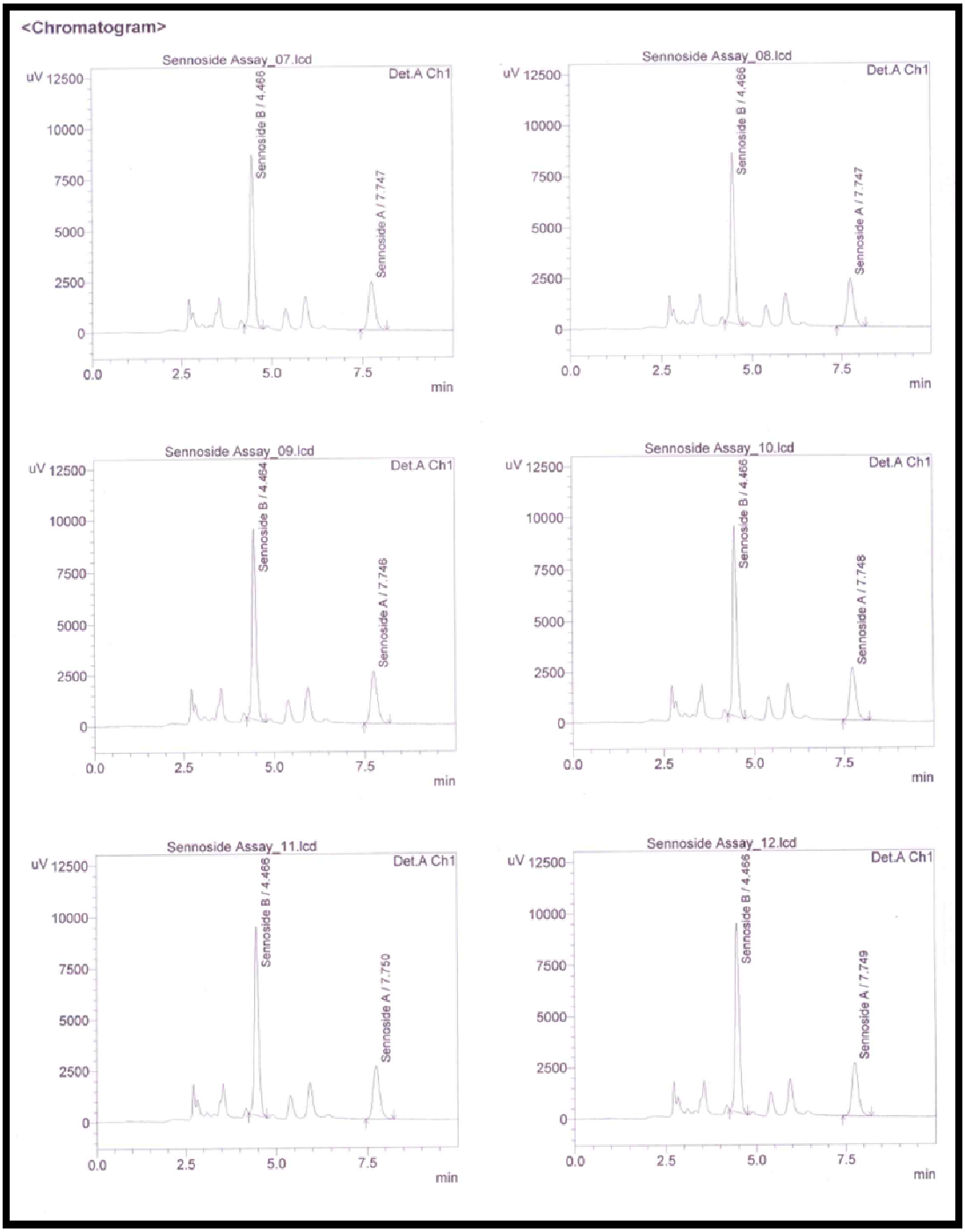
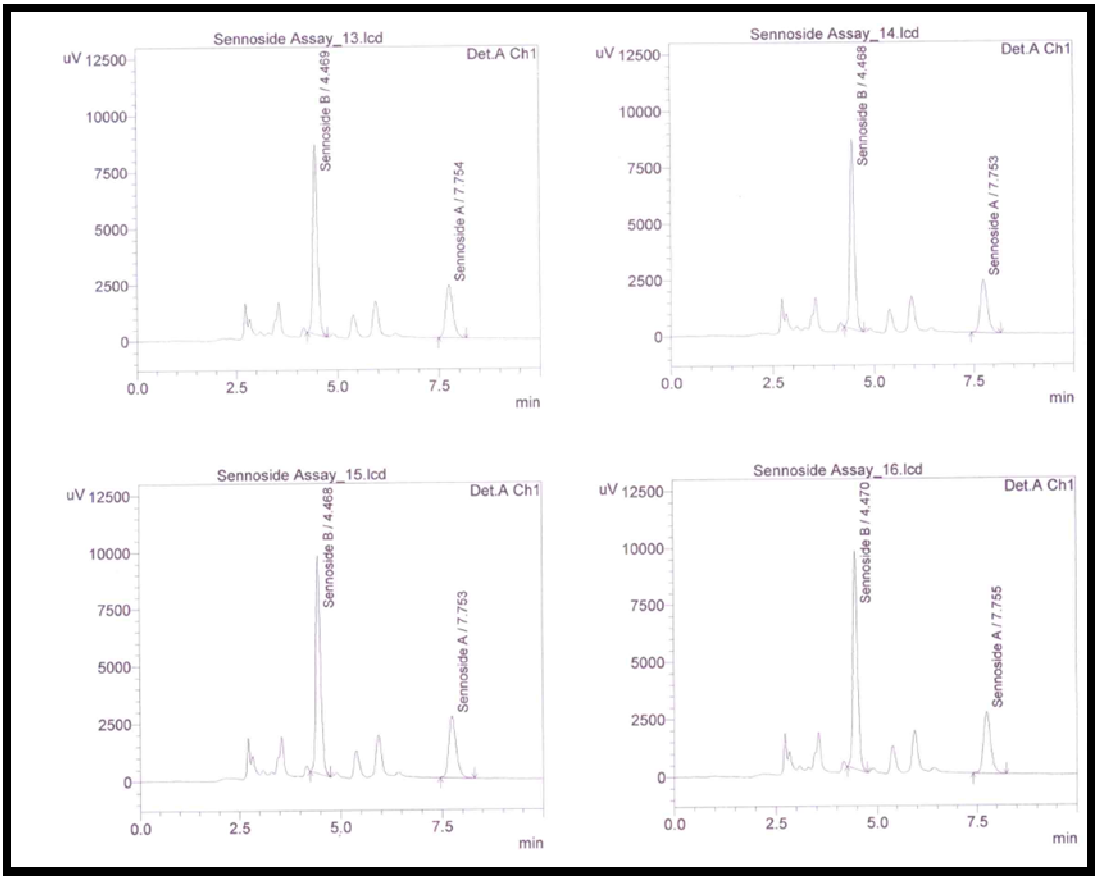


Fig.4: HPLC Graph of Formulation IV to V



DISCUSSION

The frequency and the wet weight of stools after administration of gum arabic were 22.2 ± 4.97 and 5.74 ± 1.70 g. Moreover, Formulation IV significantly increased the frequency and wet weight of stools to 31.5 ± 4.25 and 8.29 ± 1.21 g which showed tendency to increase the frequency and wet weight of stools. The frequency and the wet weight of stools following gum arabic for 14 days were 16.3±3.98 and 4.79±1.14 g respectively. Sennoside A & B capsules formulation IV significantly increased the frequency and wet weight of stools were 20.8±2.98 and 6.00±1.10 g and 25.5±5.42 and 8.09±1.91 g respectively.

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