AkiNik

International Journal of Herbal Medicine
Available online at www.florajournal.com

I J H M
International Journal of Herbal Medicine

ISSN 2321-2187
IJHM 2013; 1 (3): 8-16

Received: 16-8-2013
Accepted: 21-8-2013

S. Suresh kumar,
Department of Quality assurance, PAR Formulations Pvt. Ltd, Pudupakkam, Kelambakkam-603103, India.

Correspondence:
S. Suresh kumar,
Department of Quality assurance, PAR Formulations Pvt. Ltd, Pudupakkam, Kelambakkam-603103, India.
E-Mail: sskpharma80@gmail.com
Tel: +91-9994730693

Raw Material Standardization and Formulation Development of Polyherbal Capsule Lactare Forte

S. Sureshkumar

ABSTRACT

Plants are used as Pharmaceuticals, Nutraceuticals, Cosmetics and food supplements. Natural products are the integral part of human health care system. A galatagogue is a substance that induces lactation. It is a common term to lactation consultants and professionals and is defined as any prescription drug, herb, or food that increases a mother's breast milk supply. The aim of the study is to standardize the raw materials which are used to develop a polyherbal capsule of galatagogue and to evaluate the formulation for its standard, stability and lactation increasing capacity. Five different trail batches were formulated and were subjected to various tests like flow property, uniform filling, weight, moisture content, disintegration time. Among these formulations T-5 shows satisfactory results and this trail batch was selected for further evaluation.

Keywords: Polyherbal capsule, Galactagogue, *Lepidium Sativum* (cress), *Foeniculum vulgare* (Fennel), and *Anethum graveolens* (Dill).

1. Introduction

Lactogen [1] is substance/agents that enhances the milk secretion. Breast milk is the perfect source of nutrition for infants. Breast milk contains appropriate amounts of carbohydrate, protein, and fat. It also provides the digestive proteins, minerals, vitamins, and hormones that infants need. Breast milk contains valuable antibodies from the mother that may help the baby resist infections. **Galactagogue** [2] means that the herbs or herbal remedies that can increase the flow of milk form the breast of post-partum lady (or breast feeding mother). These herbs are used to promote or increase the secretion or flow of milk from the mammary glands of mammals. Ayurvedic Herbs and herbal remedies can increase breast milk production [3]. Besides medicinal plants, lifestyle advice is also present in ayurvedic medicine. These herbs should be used in the form of decoction or their paste or powder should be used with milk. The Aim of the present study was standardize the raw materials and to develop the Polyherbal formulation Lactare forte capsules and to set up its quality standards by evaluating its formulation parameters [4].

2. Materials and Method

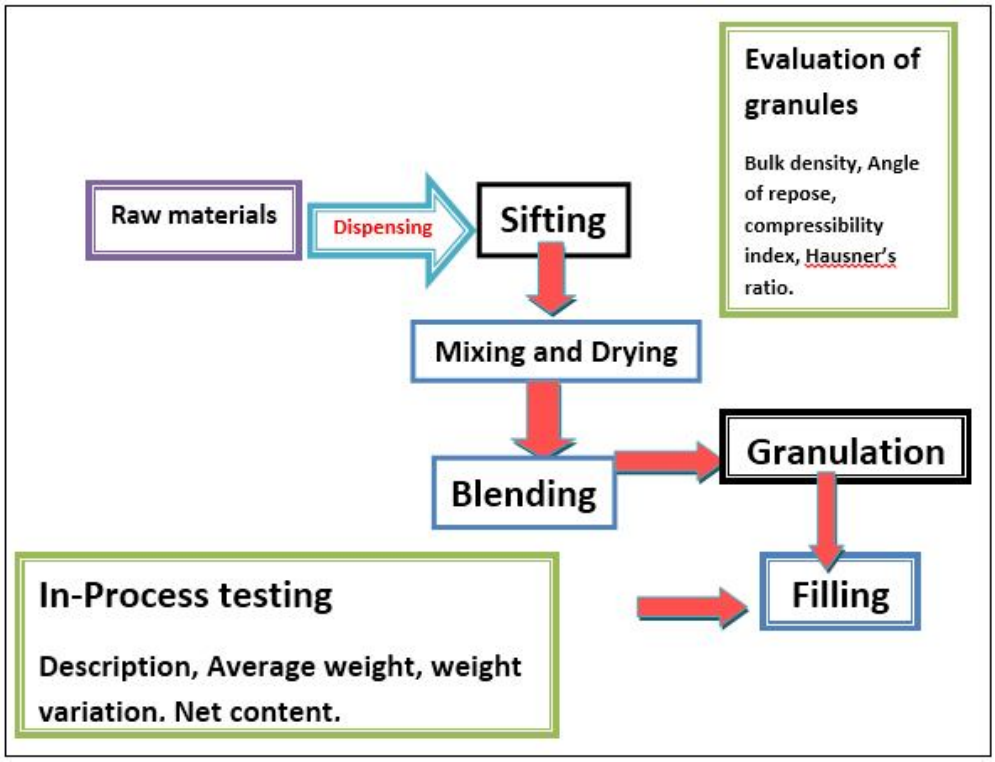
Asparagus racemosus [5], *Withania somnifera* [6], *Glycyrrhiza glabra* [7], *Trigonella foenum graceum* [8], *Allium sativum* [9] *Lepidium sativum* [10] (cress), *Foeniculum vulgare* [11] (Fennel), and *Anethum graveolens* [12] (Dill) were purchased from Absa Herbals, Chennai. Other materials used for the capsule formulation were provided by TTK Healthcare Ltd., Chennai.

3. Methods:

- Determination of Foreign Matter
- Determination of loss on drying
- Determination of ash value
- Total ash
- Acid-insoluble ash
- Determination of Extractive Value
- Water soluble extractive Value
- Alcohol soluble extractive Value
- Determination of Volatile Oil Content

3.1 Study of Color Changes under UV Light Formulation:

Five formulations of Lactare forte capsules were formulated (T-1 to T-5). Trial batches were taken by varying the composition of the Glidants. Lactare forte granules were subjected to the evaluation of bulk density, tapped density, Compressibility Index, Hausner Ratio and Angle of Repose[13]. From the samples of the Polyherbal Lactare forte capsules, the final batch (T-5) was selected and further evaluations were carried out.



3.2 Authentication using Reference samples

The raw materials used in the formulation were individually authenticated by comparing the samples with authentic samples deposited at TTK Health care R and D center.

3.3 Foreign Matter

The raw materials were analyzed for the presence of foreign materials and the results obtained given in Table 2

3.4 Loss on Drying

Loss on drying for the raw materials was done with samples taken from the suppliers .The results obtained and tabulated in Table 3.

3.5 Determination of Ash Value

Physio-chemical constants such as the ash values and extractive values for the raw materials were determined and the results obtained were recorded below.

3.6 Total ash

Total ash content of raw materials was determined, taking samples from the suppliers. The values obtained and their acceptable limits defined were given in Table 4.

3.7 Acid Insoluble Ash

From the Total ash, the Acid insoluble ash content of the individual raw materials was determined and results were given in Table 5.

3.8 Determination of Extractive Value

a) Water soluble Extractive

Water soluble Extractive values for the raw materials were determined in water and the results were given in Table 6.

b) Alcohol soluble Extractive

Extractive values for the raw materials were determined in alcohol (90 % ethanol) and the results were enumerated in Table 7.

3.9 Determination of Volatile Oil Content

Volatile oil content of the Raw materials were determined and tabulated in table 8.

3.10 Study of Color Changes under UV Light

The samples of raw materials and that of finished products were observed in UV chamber for their color changes.

Samples were divided into three parts,

- first part observed as such,
- second part observed after treating with 50% HCl

- The third part after treating with 50% NaOH.

All the observations are listed out in the Table 9.

From the table 9, it was noted that Yellow fluorescence was obtained at 254nm for Withania somnifera with 50% NaOH and 50%HCL but Asparagus racemosus shows Yellow fluorescence only with 50% NaOH among the tested samples. The difference of colour variation would help us to find adulterants and authentications.

4. Evaluation of filled capsules [14]

1. Description

Light yellow colored powder packed in "0" size Green/Green capsules.

2. Average weight

The Average weight of the capsules was given in the Table

3. Average net content of capsules

The Average net content of the capsules was given in the Table 12.

4. Determination of moisture content (KFR):

The moisture content of the capsules was given in the table 13.

4.1 Disintegration Time [15]:

The disintegration time of the capsules was given in table 14.

4.2 Weight variation

The capsules were evaluated for the flow property, weight variation, moisture content, and disintegration. The results were given in the table 15.

T-5 Lactare forte granules were subjected to the evaluation of bulk density, tapped density, Compressibility Index, Hausner Ratio and Angle of Repose.

Limit as per I.P 523mg±7.5 %(484-562mg)

1. Maximum weight: 531mg
2. Minimum weight: 520mg

5. Results:

Table 1: List of Ingredients in the formulation

S.No	INGREDIENTS	T-I (g)	T-II (g)	T-III (g)	T-IV (g)	T-V (g)
1	*Asparagus racemosus*	100	100	100	100	100
2	*Withania somnifera*	5	5	5	5	5
3	*Glycyrrhiza glabra*	10	10	10	10	10
4	*Trigonella foenum graceum*	24	24	24	24	24
5	*Allium sativum*	10	10	10	10	10
6	*Foeniculum vulgare*	10	10	10	10	10
7	*Lepidium sativum*	5	5	5	5	5
8	*Anethum graveolens*	10	10	10	10	10
9	Talc	1.33	1.33	1.33	1.67	1.67
10	Microcrystalline cellulose	-	-	17	10	10
11	Starch	33.33	23.7	-	23.33	23.33
12	Colloidal silicon dioxide	-	-	-	-	0.58
13	Lactose	-	10	11.7	-	-
14	Di calcium phosphate	-	-	5	-	-
15	Sodium benzoate	1.25	1.25	1.25	1.25	1.25
16	Sodium methyl paraben	0.5	0.5	0.5	0.5	0.5
17	Sodium propyl paraben	0.28	0.28	0.28	0.28	0.28
18	Bronopol	0.05	0.05	0.05	0.05	0.05

Table 2: Determination of foreign matter

The results were given in percentage (w/w*) NMT – Not more than* Limits were taken from Ayurvedic pharmacopoeia of India.

S.No	Ingredients	Foreign matter(%W/W)	Acceptable limit
1	*Asparagus racemosus*	0.4	NMT 1
2	*Withania somnifera*	0.5	NMT 2
3	*Glycyrrhiza glabra*	0.3	NMT 1
4	*Trigonella foenum graceum*	0.2	NMT 2
5	*Allium sativum*	0.5	NMT 2
6	*Foeniculum vulgare*	NIL	NMT 1
7	*Lepidium sativum*	0.2	NMT 2
8	*Anethum graveolens*	NIL	NMT 1

Table 3: Loss on drying for Raw Materials

S.NO	Ingredients	Loss on drying (%W/W)	Acceptable limit
1	*Asparagus racemosus*	8.41±0.14	NMT 10
2	*Withania somnifera*	6.20±0.20	NMT 8
3	*Glycyrrhiza glabra*	5.77±0.04	NMT 8
4	*Trigonella foenum graceum*	6.04±0.06	NMT 10
5	*Allium sativum*	4.80±0.22	NMT 8
6	*Foeniculum vulgare*	5.80±0.18	NMT 8
7	*Lepidium sativum*	5.80±0.02	NMT 7
8	*Anethum graveolens*	6.82±0.10	NMT 10

Table 3: Loss on Drying for Raw Materials

S.NO	Ingredients	Total ash (% w/w)	Limits (% w/w)
1	*Asparagus racemosus*	3.50±0.02	NMT 5
2	*Withania somnifera*	6.12±0.02	NMT 7
3	*Glycyrrhiza glabra*	6.60±0.01	NMT 10
4	*Trigonella foenum graceum*	2.81±0.02	NMT 4
5	*Allium sativum*	2.79±0.03	NMT 4
6	*Foeniculum vulgare*	8.65±0.02	NMT 12
7	*Lepidium sativum*	3.25±0.01	NMT 4.5
8	*Anethum graveolens*	9.84±0.03	NMT 12

Table 4: Total ash values of raw materials

S.NO	Ingredients	Acid Insoluble ash (% w/w))	Limits (% w/w)
1	*Asparagus racemosus*	0.35±0.02	NMT 1
2	*Withania somnifera*	0.28±0.01	NMT 1
3	*Glycyrrhiza glabra*	2.25±0.00	NMT 2.5
4	*Trigonella foenum graceum*	0.25±0.00	NMT 0.5
5	*Allium sativum*	0.38±0.01	NMT 1
6	*Foeniculum vulgare*	9.65±0.03	NMT 15
7	*Lepidium sativum*	0.05±0.00	NMT 0.5
8	*Anethum graveolens*	1.15±0.01	NMT 2.5

*Mean ± Standard Deviation (n=3) NMT – Not more than.*Limits were taken from Ayurvedic pharmacopoeia of India.

Table 5: Acid-Insoluble ash for Raw Materials

S.NO	Ingredients	Extractive Value (% w/w)	Limits (% w/w)
1	*Asparagus racemosus*	19.82±1.32	NLT 18.0
2	*Withania somnifera*	27.75±0.22	NLT 25.0
3	*Glycyrrhiza glabra*	22.25±0.32	NLT 20.0
4	*Trigonella foenum graceum*	3.22±0.18	NLT 2.0
5	*Allium sativum*	7.20±0.22	NLT 5.0
6	*Foeniculum vulgare*	2.22±0.11	NLT 1.0

7	*Lepidium sativum*	3.20±0.23	NLT 2.0
8	*Anethum graveolens*	17.65±0.52	NLT 15.0

Table 6: Water-soluble extractive for raw material

S.NO	Ingredients	Extractive Value (% w/w)	Limits (%w/w)
1	*Asparagus racemosus*	1.25±1.32	NLT 1.0
2	*Withania somnifera*	16.20±0.22	NLT 15.0
3	*Glycyrrhiza glabra*	15.67±0.32	NLT 10.0
4	*Trigonella foenum graceum*	6.25±0.18	NLT 5.0
5	*Allium sativum*	4.12±0.22	NLT 2.5.0
6	*Foeniculum vulgare*	5.23±0.11	NLT 4.0
7	*Lepidium sativum*	7.28±0.23	NLT 5.0
8	*Anethum graveolens*	5.19±0.52	NLT 4.0

Mean ± Standard Deviation (n=3) NLT – Not Less than

Table 7: Alcohol-soluble extractive values of Raw Material

S.NO	Ingredients	Volatile oil content (% v/w)	Limits (% v/w)
1	*Trigonella foenum graceum*	0.25	NLT 0.2
2	*Allium sativum*	0.2	NLT 0.1
3	*Foeniculum vulgare*	2.0	NLT 1.5
4	*Lepidium sativum*	0.25	NLT 0.2
5	*Anethum graveolens*	3.50	NLT 3.0

Mean ± Standard Deviation (n=3) NMT – Not more than

Table 8: Volatile oil content of raw Materials

Sample	Before any treatment			After treating with 50% HCl			After treating with 50% NaOH		
	Ordinary light	***Short UV***	***Long UV***	***Ordinary light***	***Short UV***	***Long UV***	***Ordinary light***	***Short UV***	***Long UV***
Asparagus racemosus	Light brown	Yellowish brown	Dark brown	Light brown	Yellowish brown	Dark brown	Light brown	**Yellow fluorescence**	Dark brown
Withania somnifera	Light brown	brown	Dark brown	Light brown	**Yellow fluorescence**	Dark brown	Light brown	**Yellow fluorescence**	Dark brown
Glycyrrhiza glabra	Brown	Dark brown	Blackish brown	Brown	Dark brown	Blackish brown	brown	Dark brown	Blackish brown
Trigonella foenum graceum	Brown	Yellowish brown	Dark brown	Brown	Yellowish brown	Dark brown	brown	Yellowish brown	Dark brown
Allium sativum	Off white	Yellowish brown	Dark brown	Off white	Yellowish brown	Dark brown	Off white	Yellowish brown	Dark brown
Foeniculum vulgare	Light yellow	Yellowish brown	Dark brown	Light yellow	Yellowish brown	Dark brown	Light yellow	Yellowish brown	Dark brown
Lepidium sativum	Brown	Yellowish brown	Dark brown	Brown	Yellowish brown	Dark brown	brown	Yellowish brown	Dark brown
Anethum graveolens	Light brown	Dark brown	Blackish brown	Light brown	Dark brown	Blackish brown	Light brown	Dark brown	Blackish brown

Table 9: Observation under UV light

Parameters	T-1	T-2	T-3	T-4	T-5
Bulk density (g/cm^2)	0.71±0.003	0.621±0.004	0.600±0.008	0.587±0.009	**0.52±0.002**
Tap density (g/cm^2)	0.831±0.004	0.711±0.008	0.706±0.006	0.687±0.008	**0.55±0.001**
Compressibility Index(%w/w)	20.12±1.005	19.23±1.10	15.61±1.112	12.32±1.012	**10.00±1.032**
Hausner ratio	1.1742±0.052	1.1752±0.0532	1.1352±0.0523	1.1287±0.0582	**1.12±0.022**
Angle of repose(º)	32.52±1.022	30.22±0.587	30.11±0.263	27.45±0.305	**25.16±1.022**

Table 10: Flow properties Mean ± Standard Deviation (n=3)

Formulation	*Average Weight/Capsule (mg)*
T-1*	415±0.1257
T-2*	460±0.232
T-3*	492±0.523
T-4*	523±0.148
T-5*	528±0.087

Table 11: Average weight *Mean ± S D (n=6)

Formulation	Average Net Content/Capsule (mg)
T-1*	315±2.523
T-2*	360±6.725
T-3*	392±5.213
T-4*	428±0.123
T-5*	423±0.058

*Mean ±Standard Deviation (n=6)

Table 12: Average net content/capsule

Formulation	Moisture content (% w/w)
T-1*	7.71±0.212
T-2*	9.12±0.321
T-3*	6.56±0.456
T-4*	6.47±0.121
T-5*	6.12±0.056

*Mean ±Standard Deviation (n=3)

Table 13: Moisture content

Formulation	Disintegration Time (Min)
T-1*	9.32
T-2*	10.15

T-3*	8.74
T-4*	8.22
T-5*	6.00

*Mean ± Standard Deviation (n=6)

Table 14: Disintegration Time

S. No	BATCHES/TEST	T-I	T-II	T-III	T-IV	T-V
1	Flow property	Normal	No free flow	Decreased flow	Normal	Excellent
2	Weight	Less weight	No uniform	No uniform	Uniform	Good
3	Moisture content	Within the limit	More moisture content	Within the limit	Within the limit	Good
4	Disintegration time	Within the limit	Increased time	Within the limit	Within the limit	Good

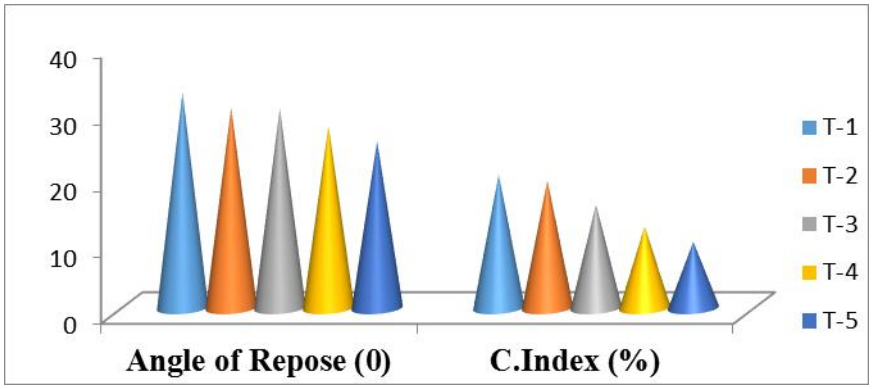


Fig 2: Flow property

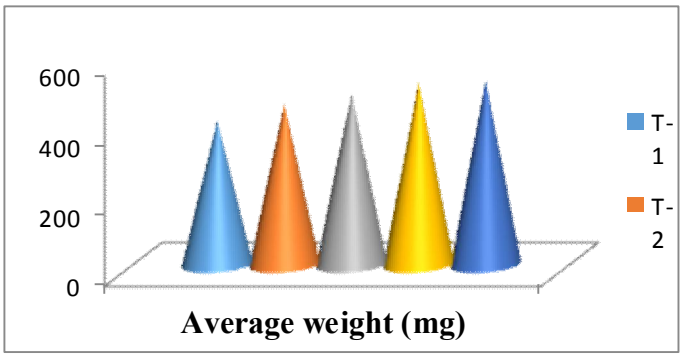


Fig 3: Average weight

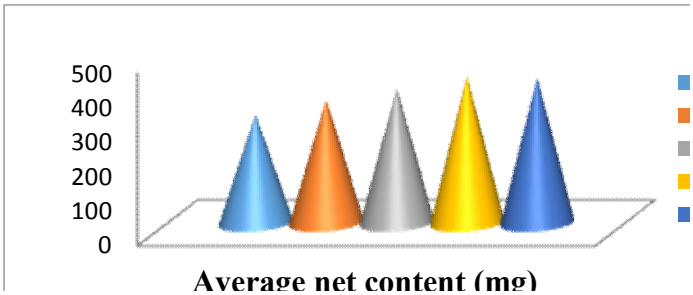


Fig 4: Average net content /capsule

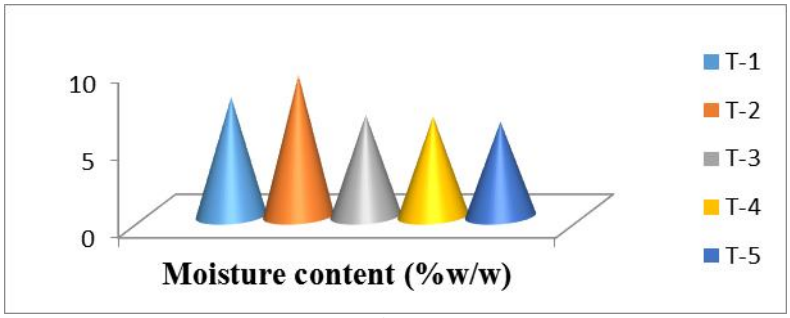


Fig 5: Moisture content

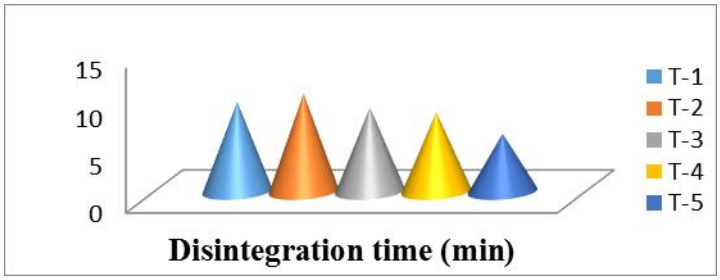


Fig 6: Disintegration Time

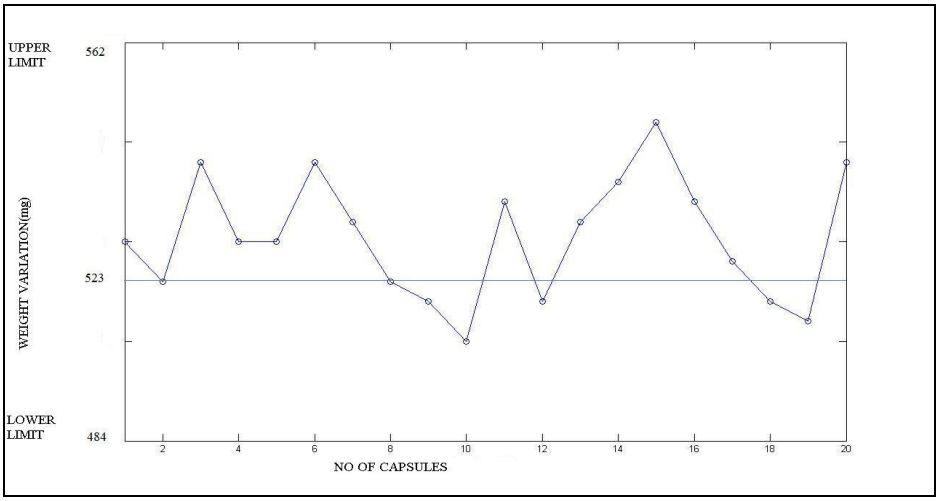


Fig 7: Weight variation of selected T-5 Lactare

5. Conclusion:

From this study a Polyherbal Lactare forte capsule was formulated with the individually standardized raw materials as per Ayurvedic Pharmacopoeia of India. The Formulation T5 was consider to a best batch as it complies with all the pharmacopoeial parameters and was selected for further study.

6. Reference:

1. Lactation Janet Talmadge, BA, IBCLC Lactation Innovation, Naperville, IL (630) P 357-0028
2. Sanjib M. Indian Medical Gazette, A double blind trial with Lactare – A lactagogue. 1987, pp.308-310.
3. Bhutani K K., "Herbal medicines an enigma and challenge to science and directions for new initiatives", Indian Journal of Natural Products, March 2003, vol.19 (1), PP3-8.
4. Patel P M., Patel N M., Goyal R K., "Quality control of herbal products", The Indian Pharmacist, March 2006, vol.5 (45)PP 26-30.
5. Sabnis Gaitonde B P and Maya Jetmalani - Effect of alcoholic extract of Asparagus racemosus on mammary glands of rats. Indian Journal of Experimental Biology (1968) 6:55-57.
6. Archana R Namasivayam A Antistressor effect of Withania somnifera. J. Ethnopharmacol. 1999; 64: PP 91-93.
7. Anjaria, J.V. and I. Gupta, Studies on lactogenic property of Leptadenia reticulata (Jivanti) and leptaden tablets in goats, sheep,cows and buffaloes. Indian Vet J., 1967. 44: PP 967–974.
8. Swafford S and Berens B. Effect of fenugreek on breast milk production. Annual meeting abstracts, 11- 13th September. ABM News and Views, 2000 ,6(3): PP 10-12.
9. The medicinal plants of india Published by the Indian council of Medical research, New delhi.india. 2008. Vol-1.
10. Tomar KS, Singh VP and Yadav RS. Effect of feeding maithy (Trigonella foenum graecum) and chandrasoor (Lepidium sativum L.) seeds on milk and blood constituents of murrah buffaloes. Indian Journal of Animal Sciences, 1996,66 :PP1192-1193.
11. Narendranath KA, Mahalingam S, Anuradha V, Rao IS. Effect of herbal galactogogue (Lactare) a pharmacological and clinical

observation. Med Surg 1986;26:PP 19-22.
12. Gurinder J Kaur et al / BMC Complementary and Alternative Medicine 2009, 910.1186/1472-6882-9-30(11).
13. United States Pharmacopoeia. The Official Standard of Compendia: 2007. 616. 30th ed. NF-25
14. Pharmaceutical dosage form, Tablets, edited by Herbert a. Liebermann, revised and expanded, Marcel Dekker, second edition, volume-3, pg no 200-216.
15. Indian Pharmacopoeia. Part-I. New Delhi: Ministry of Health and Family Welfare, Government of India; 1996. Vol-3. A-54.