



Research Article

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DESIGN DEVELOPMENT AND EVALUATION OF GALACTOGOGUE POLYHERBAL FORMULATION

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ABSTRACT

This investigation was concerned to evaluate the effect of povidone quantity on bulk density of granules, disintegration time and weight variation of filled capsules. The capsule contains Shatavari extract (*Asparagus racemosus*), Methi extract (*Trigonella foenum graecum*) and Sunthi extract (*Zingiber officinale*); which are traditionally proved as good lactate ingredients in Ayurveda. The raw materials were procured from Kisalaya Herbals, Indore, Tulsi Amrit Pvt Ltd., Indore, India and Sanat Products Ltd, New Delhi, India. Excipients were procured from Signet and National chemicals, Mumbai, India. Solid dosage form of capsule was prepared and developed for this study. The granules were prepared by wet granulation method and characterized by official method. Formulation with optimum concentration of Povidone showed good results with respect to filling property and other physical parameters were also found to be stable.

Keyword: Galactogogue, *Asparagus racemosus*, *Trigonella foenum graecum*, *Zingiber officinale*

INTRODUCTION

Breast milk has long been accepted as the gold standard of infant nutrition¹. Lactation is the process of milk production from mammary glands in female mammals^{2,3}. Mother's milk is important for survival, proper development and growth of the neonate. Milk is the only source of water, organic nutrients and minerals, to which the neonates have access. Colostrum (the first milk taken from the mammary gland after parturition) and mature milk contain non-nutrient substances (such as antibodies and bioactive factors) that are important for growth, development and survival of the neonate⁴. Galactogogues are either synthetic (Domperidone, Metoclopramide), plant derived (*Asparagus*, Fenugreek etc.) or endogenous (Prolactin) substances that increase the milk production. The chief function of lactation is to provide nutrition and immune protection to babies. Most of those discovered have been found to interact with dopamine. An inadequate or low supply of breast milk may be due to single or combined effect of inadequate or infrequent removal of milk, hormonal imbalances, damaged mammary tissue (polycystic ovarian syndrome is cause of poor mammary tissue development), scarring, stress, malnutrition, modern life style and anti galactogogues (sage, parsley, thyme, peppermint etc.)⁵ Worldwide, maternal perception of insufficient milk production is the most common reason reported by mothers for early cessation of breastfeeding⁶. For those mothers in whom milk production has declined and is not responding to non pharmacologic measures, the use of galactogogue is often considered⁷. As an alternative to pharmaceutical agents, many clinicians recommend the use of herbs to improve milk production⁸. The main advantage of herbal galactogogue is that they –

- Provide effective control by acting on various factors and pathways that lead to oligogalactia.
- Enhance both quality and quantity of milk.

- Natural, safe, and effective thus can be continued for long periods.

MATERIAL AND METHODS

Materials

- *Asparagus racemosus* extract (Shatavari) was purchased from Kisalaya herbals Ltd., Indore, India
- *Trigonella foenumgraecum* extract (Methi) was purchased from Tulsi Amrit Pvt Ltd., Indore, India
- *Zingiber officinale* extract (Sunthi) was purchased from Sanat Products Ltd., New Delhi, India
- All other excipients used were of analytical grade.

Preparation of solid dosage form i.e. capsule

Preparation of granules

Capsules were prepared by wet granulation method using Povidone (PVPK- 30) with varying concentration (0.5 % w/v, 1.0 % w/v and 1.5 % w/v) as binder. Isopropyl alcohol was used as a solvent. All extracts, Microcrystalline Cellulose, Colloidal Silicon Dioxide and Sodium Benzoate were sifted through S.S. sieve 40# and mixed in planetary mixer for 15 minutes. After mixing, the blend was granulated with the binder solution of povidone to get dough like consistency. Then the wet mass was passed through S.S. sieve 12#. The granules were dried in Fluidized bed drier. The dried granules were sifted through S.S. sieve 30# and then lubricated with Colloidal Silicon Dioxide, Talcum and Magnesium Stearate in a double cone blender.

Capsules filling operation

Final blend was filled in size "00" empty hard gelatin capsule using manual hand filling machine MF -30 (make- ACG -pam®). The batches of formulations are shown in Table 1.

Characterization of granules and capsules

The four formulations (C1, C2, C3 and C4) were evaluated for description, bulk density and tap density. Filled capsules were evaluated for weight variation and disintegration time⁹⁻¹³.

RESULTS AND DISCUSSION

The primary objective of this work was to develop polyherbal capsule of *Asparagus racemosus* (Shatavari), *Trigonella foenum graecum* (Methi) and *Zingiber officinale* (Sunthi). The development of such formulations will mark an important advancement in the area of phytopharmaceuticals. The present investigation examines design and development of solid oral herbal dosage form. The prepared batches (C1, C2, C3 and C4) were evaluated for various evaluation parameters such as bulk density, weight variation, disintegration time etc (Table 2). The prepared capsules were having acceptable elegance. The results of Bulk density showed that as the

concentration of povidone increases the bulk density also increases, but above certain concentration the bulk density again decreases. This may be because as concentration of povidone increases, the granule size increases and as the granule size increases, the void space increases, which result in lower bulk density. The results also showed that as void space increases, weight variation also increases. Formulation with appropriate bulk density is prerequisite for capsule filling. The results also showed that as the concentration of povidone increases, disintegration time increases. Since the bulk density in formulation C2 is found to be highest i.e. 0.4 g/ml, filling pressure required for "capsule filling process" is less as compared to others which makes the whole process easier. It has also been found from Table 3 that all other relative physical parameters such as disintegration time and weight variation were unaffected and were found to be fairly stable.

Table 1: Formulae for preparing capsule dosage form

S. No.	Name of ingredient	Formulation			
		C1	C2	C3	C4
1	<i>Asparagus racemosus</i> extract (Shatavari)	200 mg	200 mg	200 mg	200 mg
2	<i>Trigonella foenum graecum</i> extract (Methi)	50 mg	50 mg	50 mg	50 mg
3	<i>Zingiber officinale</i> extract (Sunthi)	25 mg	25 mg	25 mg	25 mg
4	Microcrystalline Cellulose	q.s.	q.s.	q.s.	q.s.
5	Colloidal Silicone Dioxide	7 mg	7 mg	7 mg	7 mg
6	Sodium benzoate	1 mg	1 mg	1 mg	1 mg
7	Povidone (PVP K30)	0.5 % w/v	1.0 % w/v	1.5 % w/v	2.0 % w/v
8	Talcum	7 mg	7 mg	7 mg	7 mg
9	Colloidal Silicone Dioxide	2.5 mg	2.5 mg	2.5 mg	2.5 mg
10	Magnesium stearate	4.3 mg	4.3 mg	4.3 mg	4.3 mg
	Total	430 mg	430 mg	430 mg	430 mg

Table 2: Quantitative Evaluation of capsule form of drugs

S. No.	Parameters	Observed Data For Formulations			
		C1	C2	C3	C4
1	Description	Light brown colored powder	Light brown colored powder	Light brown colored powder	Light brown colored powder
2	Bulk density	0.38 g/ml	0.4 g/ml	0.38 g/ml	0.36 g/ml
3	Tap density	0.50 g/ml	0.52 g/ml	0.48 g/ml	0.42 g/ml
4	Disintegration time	6 minutes	7 minutes	8 minutes	10 minutes
5	Weight variation of capsule	+ 0.62 %	+ 0.78 %	+ 1.24 %	+ 1.58 %

Table 3: Results of Stability Testing

S. No.	Sample No.	Month	Condition	Color/Odor	Disintegration Time
1	C1	1	40°C/75 % RH	No change	7 min
2		2	40°C/75 % RH	No change	8 min
3		3	40°C/75 % RH	No change	9 min
4	C2	1	40°C/75 % RH	No change	7 min
5		2	40°C/75 % RH	No change	8 min
6		3	40°C/75 % RH	No change	10 min
7	C3	1	40°C/75 % RH	No change	11 min
8		2	40°C/75 % RH	No change	13 min
9		3	40°C/75 % RH	No change	14 min

CONCLUSION

From above mentioned results, we can conclude that since formulation C2 with optimum concentration of povidone showed good results with respect to filling property and other physical parameters; which can be supported with the positive stability data among all formulations. Hence

the capsule form with the composition shown under C2 seems to be suitable form for *Asparagus racemosus* (Shatavari), *Trigonella foenum graecum* (Methi) and *Zingiber officinale* (Sunthi) as a promising polyherbal galactogogue in nursing mothers.

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