



Development and Evaluation of Safed Musli Formulation

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Abstract

In present communication an attempt is made to develop safed musli (*Chlorophytum borivilianum*) formulations using crude safed musli powder (SP), standardized safed musli extract (SE) and purified saponin fraction (PSF). Looking at the convenience of administration, ease of large scale production it was decided to formulate these extracts in tablet form. Different binders and diluents affected the percentage compressibility and hardness of the formulations. Formulation parameters and dissolution study results of safed musli powder tablet were compared with tablet containing safed musli extract and purified saponin fractions. SE and PSF tablet showed better dissolution than SP tablet.

Keywords: Tablet, Safed musli extract, purified saponin

Introduction

Chlorophytum borivilianum (commonly known as safed musli) belonging to family liliaceae is a very well known plant for its aphrodisiac as well as immunomodulatory activity in India.[1] Tubers of this plant holds very important position in Ayurveda and Unani system where it is mostly used to treat oligospermia, pre and post natal symptoms, arthritis, diabetes and dysuria [2, 3]. It is very good tonic to increase physical and mental health.

From, the current research available it can rightly be said that if quick steps are not taken for the preparation of commercially viable products from Safed Musli then no sooner the roots of gold may just loose their shine and glitter. As large number of ayurvedic medicinal plants have been widely studied and data generated to provide scientific basis to the traditional claims. But in majority of herbal formulations, preformulations and post formulation studies are lacking. Present study is formulating tablet using *Chlorophytum borivilianum* extract only which is proved to be having very good antistress and immunomodulatory activity.

Plant materials, extraction

Chlorophytum borivilianum roots were purchased from local cultivator and authenticated by Dr. Prabha Y. Bhogaonkar (Director, Government Vidarbha Institute of Science and Humanities, Amravati). The roots were dried, powdered and defatted by petroleum ether. Marc then extracted with methanol for 3 hour with mild heating. The MeOH solution was concentrated under reduced pressure, below 45°C, to dryness. The resulting crude MeOH extracts (ME) was further fractionated to give purified saponin fraction (PSF). All three safed musli powder, methanolic extract and purified saponin fraction stored in tight container till its use.

Material and Methods

MCC, co-crystallised lactose, starch, talc, Mg-stearate were purchased from Loba chem. (Mumbai, India). All other chemical used were of analytical grade. UV Spectrophotometer (Shimadzu) and tablet punching machine (Rimek minipress) were used for the present study.

Formulations of Safed musli powder (SP) tablet

Tablets of *Chlorophytum borivilianum* powder were prepared by wet granulation method. Two different diluent were used i.e. co-crystallised lactose and mixture of co-crystallised lactose-MCC (80:20). The mg-stearate was added as lubricant and talc as glidant while PVP and starch as a binder. The composition of different formulations used in the study is given in Table 1. The powder, co-crystallised lactose, MCC and the polymer were passed through 60# sieve and then and granulated with binder. The wet mass was passed through a mesh and the granules were dried at 50°C for 2 hours. These granules were lubricated in poly bag using talc and Mg-stearate. Desired quantity of granules were weighed and fed manually to compression machine and granules compressed into tablets on a 10-station single rotary Rimek minipress machine. The flat faced punch i.e. upper punch with break line and plane lower punch of diameter 10 mm was used for compression.

Formulation of Safed musli extract (SE) tablet

The tablets of *Chlorophytum borivilianum* extract prepared by wet granulation method. The SE tablets again developed by using two different diluents i.e. co-crystallised lactose, and mixture of co-crystallised lactose-MCC (80:20). Mucilage present in extract allowed good binding properties. This blend further compressed as above. The SE tablets prepared by wet granulation were evaluated for preformulation and postformulation parameters. Angle of repose, total porosity, Carr's index, bulk density, tap density, friability, weight variation, hardness, disintegration were measured. (Table 2)

Formulation of Purified saponin fraction (PSF) tablet

The tablets of PSF prepared by wet granulation method. Same procedure was followed as in case of SE tablet. The SPF tablets were evaluated for various formulation parameters. Angle of repose, total porosity, Carr's index, bulk density, tap density, friability, weight variation, hardness, disintegration were measured. (Table 3)

Evaluation of tablets [4]

Granules were evaluated for various evaluation parameters like angle of repose, Hausner's ratio and Carr's index. The prepared tablets were evaluated for hardness, friability and drug content.

Hardness of the tablets was tested using a Monsanto hardness tester (Tab-machine, Mumbai). Friability of the tablets was determined in a Roche friabilator (Campbell Electronics, Mumbai).

***In-Vitro* dissolution study of prepared tablets**

The *in vitro* dissolution studies were carried out using USP 24 dissolution apparatus type II (paddle method) at 100 rpm using distilled water as a dissolution medium. Total saponin released was analyzed by a previously reported standard method [5] with purified saponin as standards. The results of dissolution study were given in table 4.

Results and Discussion

Phytochemical study of extract shows presence of carbohydrates, alkaloids, saponin glycosides, mucilage and phytosterols. Since, saponin constitute are major chemical entity in *Chlorophytum borivilianum*, we thought it logical to evaluate our formulation with respect to total saponin content. Saponin content can be taken as a reliable and reproducible parameter for the dissolution study of the *Chlorophytum borivilianum* formulation.

As all selected extract formulated in tablet by both direct compression and wet granulation method. SP tablets prepared by direct compression method showed poor compressibility (Carr's index) and flowability (angle of repose) with selected diluents. And hence formulation SP1 and SP2 further not evaluated. But by wet granulation method, formulation SP3 and SP6 showed good tablet properties as compared to formulation SP2 and SP4. Starch paste did not give satisfactory results (Table 1). Polyvinyl pyrrolidone at 2% and 5% showed better tablet characteristics, friability and crushing strength.

Table 1: formulation and evaluation parameters of safed musli powder (sp) tablets

Formula	SP1	SP2	SP3	SP4	SP5	SP6
Powder	500	500	500	500	500	500
Diluent	L-50	LM-50	L-50	LM-50	L-50	LM-50
Binder	-	-	PVP 2%	ST 2%	ST 5%	PVP 5%
Glidant	2%					
Lubricant	1%					
Hausner's ratio	1.56	1.50	1.37	1.34	1.43	1.48
Carr's index (I)	36	34	27	26	30	32
Angle of Repose (Θ)	32.6	31.8	33.4	32.17	34.21	30.12
Hardness (Kgf)	-	-	5.4	5.2	5	5.4
Friability (%)	-	-	0.11	0.23	0.29	0.19
DT	-	-	13	11	12	10

In case of SE tablets both direct compression and wet granulation method gave good results. But in commercial point of view to reduce processing steps direct compression is found to be better for SE tablet formulation. The results revealed that Co-crystallized lactose- MCC give the lowest Carr's Index and angle of repose (Table 2). Thus it can be concluded that co-crystallized

lactose-MCC gives better compressibility and flow properties as compared to MCC. Mucilage present in extract allowed good binding properties and tablets showed no capping. Hence less concentration of binder (2%) is required to give good tablet properties. Results also clear that alcoholic PVP (2 and 5%) is more effective binder as compared to starch paste (Table 2). Thus formulation SE2 is ideal formulation.

Table 2: formulation and evaluation parameters of safed musli extract (se) tablets

Formula	SE1	SE2	SE3	SE4	SE5	SE6
Extract	300	300	300	300	300	300
Diluent	L-100	LM-100	L-100	LM-100	L-100	LM-100
Binder	-	-	PVP 2%	ST 2%	ST 5%	PVP 5%
Glidant	2%					
Lubricant	1%					
Hausner's ratio	1.27	1.22	1.37	1.30	1.34	1.25
Carr's index (I)	21.7	18	27	23	26	20
Angle of Repose (Θ)	30.21	29.12	31.5	32.3	34.12	28.32
Hardness (Kgf)	5.2	5.4	6.2	6.1	6	6.4
Friability (%)	0.23	0.2	0.11	0.15	0.16	0.1
DT	12	11	13	09	12	10

Table 3: formulation and evaluation parameters of purified saponin fraction (psf) tablets

Formula	PSF 1	PSF 2	PSF 3	PSF 4	PSF 5	PSF 6
Extract	150	150	150	150	150	150
Diluent	L-100	LM-100	L-100	LM-100	L-100	LM-100
Binder	-	-	PVP 2%	ST 2%	ST 5%	PVP 5%
Glidant	2%					
Lubricant	1%					
Hausner's ratio	1.34	1.30	1.29	1.37	1.35	1.25
Carr's index (I)	26	23	22	27	26	20
Angle of Repose (Θ)	34.5	37.3	30.6	33.8	34.23	31.6
Hardness (Kgf)	4.5	4.8	5.2	4.8	4.9	5.4
Friability (%)	0.42	0.34	0.32	0.35	0.4	0.3
DT	11	10	13	12	14	11

Tablets of PSF prepared by wet as well as direct compression method showed good tablet properties but wet granulation is more suitable to obtain better results. Here again alcoholic PVP (2 and 5%) is more effective binder as compared to starch paste (Table 3). From granule and tablet properties it is concluded that Co-crystallized lactose-MCC is best diluent for formulation of PSF tablet. PSF3 and PSF6 are ideal formulation.

Table 4: comparison of percent release of total saponins from the formulation of safed musli powder, safed musli extract and purified saponin extract

Formulation	Content of total saponins	Percent release of saponins
SP6	17.8 ± 0.2	57.9 ± 0.6
SE2	62.3 ± 0.3	85.2 ± 0.4
PSF6	94.9 ± 0.4	96.1 ± 0.21

Conclusion

In conclusion, Co-crystallized lactose-MCC and alcoholic PVP proved to be best diluent and binder respectively. Tablets of safed musli powder showed high friability compared to tablets of safed musli extract and purified saponin fraction extract. In dissolution study also SE and PSF tablets exhibited better performance. The proposed formulation has distinct advantages such as concentrated actives, compact tablet form, ease of handling and administration etc.

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