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STABILITY STUDIES OF SOME NEW POLYHERBAL TABLET FORMULATIONS FOR THE TREATMENT OF DIABETES AND HYPERLIPIDEMIA

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ABSTRACT

This study involved formulating five different polyherbal tablets (F1 to F5) using three standardized extracts: *Momordica charantia* (which contains 3% bitter principle), *Cinnamomum cassia* (10% total phenols), and *Stevia rebaudiana*. The tablets used wet granulation with microcrystalline cellulose (MCC PH101) as a diluent, Povidone K30 as a binder, and magnesium stearate and talc as glidants. To evaluate the tablets, methylparaben (0.1% to 0.2%) and propylparaben (0.1% to 0.25%) were used to create different tablet compositions (F2 to F5). The tablets were then tested for precompression parameters (angle of repose, bulk density, tapped density, and compressibility index) and post-compression parameters (weight variation test, friability test, hardness test, and stability studies). All formulations (F1 to F5) met the required specifications and were found to be stable for up to 90 days. The tablets containing propylparaben (F4&F5) were harder and less friable than those containing methylparaben (F2&F3), indicating better dissolution. The concentration of preservatives affected the tablets.

Keywords: Polyherbal, Momordica, Cinnamon, Stevia, Formulations

INTRODUCTION

One of the most significant health issues in recent times is diabetes mellitus **[1]**. However, the conventional methods of treating diabetes and hyperlipidemia using synthetic drugs have proven to be insufficient and can lead to serious side effects **[2, 3]**. Fortunately, numerous indigenous Indian plants such as Momordica and Cinnamon have been found to have the potential to treat these conditions and successfully manage diabetes **[4, 5]**. However, most existing polyherbal formulations use crude drug powders, which are not standardized **[6]**. There is a clear need to develop standardized polyherbal formulations using extracts rather than crude powders to ensure consistency in potency and efficacy **[7]**. For the preparation of such standardized herbal formulations, one needs to incorporate standardized extracts instead of crude powders **[8]**. Hence there is a need to develop formulations with extracts of herbs. Further, the existing antidiabetic polyherbal formulations containing Momordica suffer from a bitter taste. Hence there is a need to improve the palatability of such polyherbal formulations using natural sweetening agents like Cinnamon, Stevia, etc., and thus increase patient compliance **[9, 10]**. The present work aims to study the impact of preservatives **[11]** on the stability of new polyherbal tablets that contain selected plants, including *Momordica charantia*, *Cinnamomum cassia*, and *Stevia rebaudiana*.

MATERIALS AND METHODS

Plant Materials:

Momordica charantia (Standardized fruit extract containing 3% bitter principle), *Cinnamomum cassia* (Standardized Bark extract containing 10% total phenol) and *Stevia rebaudiana* were purchased from Natural Remedies Pvt Ltd. Bangalore, Karnataka, India.

Chemicals: Aerosil was procured from ASR Agri Exports Pvt Ltd. Hyderabad, Polyvinyl pyrrolidone, Microcrystalline cellulose (Avicel FMC type PH-101), Magnesium stearate, Methylparaben, Propylparaben and Talc were purchased from Finer Chemicals Pvt Ltd. Ahmedabad.

Formulation of tablets:

Tablets were formulated separately by wet granulation method using different compositions of ingredients mentioned in **Table 1** and blended for 10 min. Then, 5% PVP was added to isopropyl alcohol and this mixture was added to the blended mixture. It was passed through mesh no.16 to prepare granules and dried at 50^0C for 1h 30 min. Dried granules were passed through mesh no. 18. They were mixed with accurately weighed quantities of aerosil, magnesium stearate, and talc, and blended for a few minutes **[12]**. Tablets are compressed on a 10-station Mini press-1 rotary tablet compression machine fitted with 8-mm flat-shaped punches.

Table 1: Polyherbal formulations

Formulation 1	Formulation 2	Formulation 3	Formulation 4	Formulation 5
Momordica (3% bitter principle)- 200mg	Momordica (3% bitter principle)- 200mg	Momordica (3% bitter principle)- 200mg	Momordica (3% bitter principle)- 200mg	Momordica (3% bitter principle)-200mg
Cinnamon- 150mg	Cinnamon-150mg	Cinnamon-150mg	Cinnamon-150mg	Cinnamon-150mg
Stevia-50mg	Stevia-50mg	Stevia-50mg	Stevia-50mg	Stevia-50mg
MCC PH 101 -20mg	MCC PH 101 -20mg	MCC PH 101 -20mg	MCC PH 101 -20mg	MCC PH 101 -20mg
PVP (K 25)- 5%	PVP (K 25)- 5%	PVP (K 25)- 5%	PVP (K 25)- 5%	PVP (K 25)- 5%
Aerosil-3mg	Aerosil-3mg	Aerosil-3mg	Aerosil-3mg	Aerosil-3mg
Isopropyl alcohol	Isopropyl alcohol	Isopropyl alcohol	Isopropyl alcohol	Isopropyl alcohol
Magnesium stearate – 3mg	Magnesium stearate – 3mg	Magnesium stearate – 3mg	Magnesium stearate – 3mg	Magnesium stearate – 3mg
Talc – 3mg	Talc – 3mg	Talc – 3mg	Talc – 3mg	Talc – 3mg
---	Methyl paraben- 0.1%	Methyl paraben- 0.2%	Propyl paraben-0.1%	Propyl paraben- 0.25%

RESULTS AND DISCUSSION

Evaluation of tablets:

Micromeritic properties **[13-15]** were determined using a physical mixture of F-1 to F-5 and all of them have shown good results **(Table 2)**. The results of bulk density are found to be in the range of 0.41-0.5 kg/l. The highest bulk density was observed for F1 and the lowest for F-2 and F-5 granules. Tapped density and Carr's index were found to be in the range of 0.43 to 0.59 kg/l and 12 to 14, respectively. F-5 granules exhibited the highest values and F-1 lowest **[13]**. The angle of repose ranged from 31.75 to 36.21 for F-1 to F-5 indicating that they have fair to excellent flowability. Hausner's ratio was found to be between 1.03 to 1.17, a lower value indicates better flowability and a higher value indicates poor flowability and it was found to be better for F-2 than F-1.

All post-compression parameters were evaluated and values were compared with the standard value formulations in a plastic container and signs of degradation of the specific dosage forms were observed monthly and values were reported based on their appearance, friability, and colour **[16-19]**. The results of the appearance, weight variation, hardness, friability, and dissolution of the tablets are given in **Table 3**. All the samples complied with the official requirements of uniformity of weight. The observed friability of tablets F1 to F5 was found to be in the range of 0.51% to 0.66% during the period of study. All formulations showed an increase in %friability from 30 to 90 days. If the change in friability is less than 1%, they are considered acceptable. So, the tablets F-1 to F-5 are less friable. Their low friability indicates that the tablets are compact and hard. The results are similar, even on tablets that had been stored for 3 months at 40°C and 70% relative humidity. There was a significant change in % dissolution of tablets from 1st month to 3rd month. The % dissolution after the 4th hour

decreased from 30 days to 90 days for tablets F-1 to F-3 whereas it increased for propylparaben-containing tablets F-4 to F-5. The hardness of the formulation F-1 to F-5 was found to be in the range of 1.52-1.74 kg/cm^2 during 1st month, 2.27- 2.29 kg/cm^2 2nd month, and 3.52-3.78 kg/cm^2 during 3rd month. It indicates that propyl paraben tablets (F4 & F5) were found to be harder than methylparaben tablets (F2 & F3). The appearance of tablets F1 to F5 changed from greyish brown to black over 3 months.

Table 2: Micromeritic properties of table blend

Batch	Bulk density (Kg/L)	Tapped density (Kg/L)	Carr's index	Angle of repose	Hausner's ratio
Formulation-1	0.5	0.43	12	31.75	1.17
Formulation-2	0.41	0.54	13	33.16	1.03
Formulation-3	0.49	0.56	15	35.18	1.08
Formulation-4	0.48	0.51	12.5	34.18	1.12
Formulation-5	0.41	0.59	14	36.21	1.15

Table 3: Accelerated stability studies of polyherbal formulations

Batch	F1	F2	F3	F4	F5
Month 1: Appearance of all Formulations (Greyish brown, flat circular bevel-edged uncoated herbal tablet)					
Weight Variation (mg)	199	199	199.5	199	199
Hardness (kg/cm^2)	1.52	1.54	1.68	1.49	1.74
Friability (%)	0.51	0.54	0.55	0.54	0.58
Dissolution (%)	2nd Hr- 54 4thHr-89.6	2nd Hr- 42.6 4thHr- 70.6	2nd Hr- 44 4thHr-71.2	2nd Hr- 46 4thHr-73.6	2nd Hr- 47 4thHr-77.4
Month 2: Appearance of all Formulations (Light black, flat, circular bevel-edged uncoated herbal tablet)					
Weight Variation	199	198.5	198	198.7	198.2
Hardness (kg/cm^2)	2.27	2.36	2.59	2.57	2.96
Friability (%)	0.52	0.59	0.62	0.57	0.66
Dissolution (%)	2nd Hr- 56 4thHr- 82.6	2nd Hr- 40 4thHr- 72.6	2nd Hr- 41 4thHr- 73.6	2nd Hr- 40 4thHr- 72.1	2nd Hr- 40.7 4thHr- 70.8
Month 3: Appearance of all Formulations (Black, flat, circular bevel-edged uncoated herbal tablet)					
Weight Variation	198.2	200	199.7	199.2	200
Hardness (kg/cm^2)	3.52	3.54	3.68	3.70	3.78
Friability (%)	0.52	0.57	0.68	0.59	0.65
Dissolution (%)	2nd Hr- 55 4thHr- 82.7	2nd Hr- 36.6 4thHr- 64.6	2nd Hr- 39 4thHr- 69.7	2nd Hr- 42 4thHr- 81	2nd Hr- 89 4thHr- 80.6

CONCLUSION

This study focused on developing and evaluating five polyherbal tablet formulations (F1 to F5) for the treatment of diabetes and hyperlipidemia, utilizing standardized extracts of *Momordica charantia*, *Cinnamomum cassia*, and *Stevia rebaudiana*. The inclusion of preservatives, specifically methylparaben (in F2 and F3) and propylparaben (in F4 and F5), had a noticeable impact on tablet performance. Tablets containing propylparaben exhibited higher hardness and lower friability, indicating better mechanical strength compared to those with methylparaben.

Dissolution studies revealed that propylparaben-containing formulations (F4 and F5) showed improved dissolution rates over time, even after 90 days, while the methylparaben-containing tablets

experienced a slight decline in dissolution performance. Despite a change in appearance from greyish brown to black over the course of stability testing, there was no significant impact on the core properties of the tablets.

The study concludes that all five formulations are stable and meet the required pharmaceutical standards for polyherbal tablets. However, the formulations containing propylparaben demonstrated superior stability and performance, making them more suitable for long-term storage and potential therapeutic use. These findings suggest that propylparaben-containing polyherbal tablets could be effective for managing diabetes and hyperlipidemia, offering a promising alternative for future herbal medicine development.

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