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Research Article

# FORMULATION DEVELOPMENT OF ORO-DISPERSIBLE TABLETS OF AYURVEDIC POWDER FORMULATION FOR EFFICIENT USE

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**ABSTRACT**

The aim of this study was to formulate mouth dissolving tablets from Ayurvedic polyherbal powder Sitopaladi. Sitopaladi is a traditional Ayurvedic powder preparation well known and effective in relieving coughs associated with various respiratory disorders. Being a powder the administration of accurate dose with ease is a problem. Furthermore it needs water and chances of spoilage and waste are more. Oro-dispersible tablet which rapidly disintegrating in mouth will be the best remedy for efficient use of Sitopaladi. Using various excipients like super-disintegrants and sweeteners, different formulation of anti-tussive drug Sitopaladi were formulated by direct compression method. The acceptable formulation, among all the developed formulations of oro-dispersible tablet was having a disintegrating time of 1 min and 30 sec and acceptable taste. Thus the study concludes that formulation of oro-dispersible tablets of ayurvedic powder preparation can be a good option to enhance acceptability, efficiency and easy and accurate administration of powder ayurvedic preparations like Sitopaladi.

**Keywords**: Sitopaladi, oro-dispersible, ayurvedic, cough, polyherbal powder.

## INTRODUCTION

Oral route of administration of drug is the most popular method because of patient compliance and convenience in administration of drug. And solid formulations like powders, tablets and capsules etc are mostly formulated and prescribed to the patients to be administered by oral route. But because of unpalatable taste of drugs and difficulty in administration and swallowing in case of geriatric, pediatric, bed ridden patients, the drug cannot be given as such in oral conventional formulations may it be tablet or powders. Powders have also problem of administration of accurate dosage and with ease due to their fine particulate nature. There are chances of spilling and spoiling and spreading all over with powder formulations especially bulk powders. This leads to decrease in patient compliance. To overcome this, a new approach i.e. development of mouth dissolving/dispersing solid formulations have generated a lot of research interest. In these formulations, some of the drug gets absorbed through pharynx and esophagus while it is travelling to the stomach thus increasing the bioavailability and making it more beneficial than other conventional tablet dosage forms[1,2].Oro-dispersible[3,4,5] tablets are one of the kind of formulations. These tablets get disintegrated in the saliva and dissolve[6,7,8]. These tablets are formulated with super disintegrants to aid rapid disintegration, sweetening agent to mask the bitter taste, making it palatable and flavoring agent to leave a pleasant taste and feel in the mouth.

Sitopaladi is a ayurvedic polyherbal powder used to cure cough, asthma and other disorders of respiratory tract [9,10,11] . Most of the ingredients present in the powder like Long pepper and cinnamon are reported to have immune-modulators activity also act as bioenhancer. These Ayurvedic powders are taken 1-1/2 teaspoon along with honey because of the problem in administrating powder as such and unpalatable taste. So to avoid the rigorous task of carrying drug and honey, to avoid the drug adherence issue and various other disadvantages which arise due to Ayurvedic formulation these powder formulations are converted into MDT's which have sufficient hardness, fast disintegration rate and pleasant taste [12,13,14].

## MATERIALS AND METHODS

Sitopaladi powder was purchased from Wonder Herbals Ltd Hyderabad india . All the other excipients were procured from S. D. Fine Chemicals Mumbai India . All reagents were of AR grade and used as received.

### Preparation of Oro-dispersible Tablets

Orodispersible tablets of shitopaladi powder were prepared as per the formula given in **Table 1.** Accurately weighed quantities of drug, mannitol, crospovidone and diluents were passed through sieve number 100 and mixed in a glass mortar. The drug and directly compressible excipient were mixed by adding small portion of each at a time and blending it to get a uniform mixture. The other ingredients were mixed in geometrical order but magnesium stearate and talc were added at the last and mixed for further two minutes The blend was air-dried and compressed using CADMACH 8 punch rotary tablet machine at a fixed compression force. The mean weight and diameter of the tablets were 660 mg and 9 mm, respectively.

### Evaluation of Tablets

All the formulation batches of oro-dispersible tablets were evaluated for the following parameters:

**Weight Variation:** weight variation test can be a measure of uniformity of content. For this test, twenty tablets were randomly selected from each batch and individually weighed. The average weight of these selected tablets was calculated.

**Hardness:** Tablet crushing strength, which is the diametric force required to break the tablet, was measured with a Pfizer tablet hardness tester. The hardness (crushing strength) of three tablets per batch was determined and mean taken.

**Friability:** friability is measure of strength of tablet. Tablet friability was measured using a ROCHE friabilator (USP) at 25 rpm for 4 min. The weight of ten tablets before and after completion of the test was recorded and friability was calculated by the following formula:

Percentage friability= (initial weight-final weight/initial weight) ×100 …… (1)

**Disintegration time:** Three tablets per batch were evaluated for disintegration time by employing a digital disintegration apparatus. Water (1000 ml), maintained at 37±0.5 0C was used as disintegrating. Disintegration time was recorded when all the fragments of the disintegrated tablet passed through the screen of the basket.

**Palatability Test**

The palatability of the formulated MDT's was tested by Panel Method[15]. In this method 10 subjects were randomly selected and their mouth was cleansed with purified water. Tablets formulated were placed on each of the subject's tongue and taste was evaluated after 10 seconds. The taste of a pure drug is used as a standard and the degree of bitterness of formulated tablets is judged by the volunteers. The results are classified as below,

+ = excellent taste masking. ;
++ = slightly bitter;
+++ = very bitter.

**Table 1: Formula for various formulation of tablets (data in mg)**

| Ingredients | F1 | F2 | F3 | F4 | F5 | F6 | F7 |
|---|---|---|---|---|---|---|---|
| Sitopaladi | 500 | 500 | 500 | 500 | 500 | 500 | 500 |
| PVP | 30 | 30 | 30 | 30 | 20 | 20 | 20 |
| Mannitol | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Lactose | 12 | 12 | 12 | 12 | 10 | 10 | 10 |
| Corn Starch | 66 | - | - | - | - | - | - |
| Sodium Starch Glycolate | - | 66 | - | - | 80 | - | - |
| Croscarmellose Sodium | - | - | 66 | - | - | 80 | - |
| Crospovidone | - | - | - | 66 | - | - | 80 |
| Magnesium Stearate | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| Talc | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| Trisodium Citrate | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Sodium Saccharine | 10 | 10 | 10 | 10 | 8 | 8 | 8 |

## RESULTS AND DISCUSSIONS

All the results of various evaluator tests are shown in **Table 2**. From the results of the evaluation test of the tablets it can be observed that mannitol is a good diluents as it forms smooth and relatively strong tablets which disintegrate easily and rapidly when come in contact with disintegrating fluid. This is probably due to its water soluble nature as suggested by Debord et al[16].

It was also observed that among the various disintegrants used such as Corn starch, Crospovidone, Croscarmellose Sodium and Sodium Starch Glycolate, Crospovidone shows relatively faster disintegration time at same concentration as compared to others. It might be due to high water uptake capacity and low gelling capacity of Crospovidone[17] when compared to others. Difference in swelling may also play a role in disintegrating agent efficiency It causes the tablet to disintegrate quickly.

**Palatability Test**

The prepared films were given to volunteers of different age groups between 20 to 40yrs and evaluated for effectiveness of taste masking. Results showed that excellent taste masking was achieved with all formulations. Taste evaluation study of mouth dissolving films by panel method revealed that about 80% of the volunteers sensed no bitter taste. The results of taste evaluation by panel method are shown in **Table 3.**

**Table 2: Evaluation results of prepared tablets**

| Parameters | F1 | F2 | F3 | F4 | F5 | F6 | F7 |
|---|---|---|---|---|---|---|---|
| Weight variation | 650±1.31 | 650±1.01 | 650±1.44 | 650±3.81 | 650±0.96 | 650±1.78 | 650±1.98 |
| Hardness ($Kg/cm^2$) | 2.30±0.31 | 2.18±0.61 | 3.44±0.56 | 2.63±0.23 | 2.36±0.43 | 3.24±0.87 | 2.43±0.58 |
| Friability (% w/w) | 1.41 | 1.32 | 1.34 | 2.36 | 1.46 | 1.08 | 1.31 |
| Disintegration Time (sec) | 9.41±0.33 | 5.41±0.41 | 5.32±0.22 | 5.20±0.36 | 4.32±0.51 | 2.20±0.71 | 1.31±0.63 |

**Table 3: Palatability results for Sitopaladi Tablets**

| Volunteers | V1 | V2 | V3 | V4 | V5 | V6 | V7 | V8 | V9 | V10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Powder | ++ | +++ | +++ | +++ | ++ | ++ | +++ | +++ | ++ | ++ |
| Tablet | 0 | 0 | + | + | 0 | 0 | 0 | 0 | 0 | 0 |

**+++ = very bitter ; ++ = bitter ; + = slightly bitter; 0 = no bitter taste**

## CONCLUSION

The study was successful in formulation of mouth dissolving tablets of Sitopaladi by direct compression method and using different super disintegrants. The aim of the study was to produce tablets that have palatable taste which is the major disadvantage of Ayurvedic formulations and this was successfully achieved. Thus it can be concluded that Ayurvedic formulations can be converted to ODT's using different suitable excipients.

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