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Research Article

# Formulation and Evaluation of tablet of a Classical Fermented Preparation of Dashmularishta

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## Abstract

Dashmularishta is a fermented liquid preparation made with the various ingredients in the formulation composition. It is rejuvenator and revitalizer and commonly known as restorative tonic. It relives post delivery weakness. It contains not more than 10%, and not less than 5% of alcohol that is self generated in the preparation over a period of time. This syrup promotes vitality and strength. It improves milk production in women's. This is very useful in menopause. Dashmularishta restores energy in women after delivery. This is a tonic made from different herbs. It helps in removing toxins from body and nourishes body tissues. It maintains healthy female reproductive system. It is also a curative for general weakness. It combines synergistic benefit of Dashmool with other herbs. The present study involved the preparation of conventional tablet of Dashmularishta. Decoction of all the herbs was prepared in the boiler. Decoction was concentrated by use of falling film evaporator. Powder from the concentrated decoction was prepared by Spray drier. Tablets were prepared by direct compression. Dashmularishta tablets each weighing 475 mg containing 325 mg of drug was formulated. Lubricated blends were characterized for physical properties like loose bulk density, tapped density, angle of repose, Carr's index, Hausner´s ratio; all blends showed satisfactory properties. Tablets were evaluated for uniformity of weight, thickness, hardness, percentage (%) friability and in vitro release studies.

**Keywords:** - : decoction, spray drier, Carr's index, Hausner´s ratio, angle of repose etc..

## INTRODUCTION

Dashmularishta is a fermented liquid preparation made with the various ingredients in the formulation composition. It is rejuvenator and revitalizer and commonly known as restorative tonic. It relives post delivery weakness. It contains not more than 10%, and not less than 5% of alcohol that is self generated in the preparation over a period of time. This syrup promotes vitality and strength. It improves milk production in women's. This is very useful in menopause. Dashmularishta restores energy in women after delivery. This is a tonic made from different herbs. It helps in removing toxins from body and nourishes body tissues. It maintains healthy female reproductive system. It is also a curative for general weakness. It combines synergistic benefit of Dashmool with other herbs. It strengthens the myometrial muscles in uterus, which enables to achieve adequate uterine contraction too expel menstrual discharge. Dashmularishta is useful in reliving mild to moderate pain in cases of dysmenorrhea. It is recommended in cases of infertility. It provides strength to post natal women and help uterus to regain normal size and shape. It is a clear dark brown coloured powder. The pH of the formulation is 4.0 to 4.2. The total phenolic content is 0.2% w/v in the formulation. It is very soluble in water. The total solids present in the formulation are 24-54% w/v and reducing sugar is 14-24% as well as non reducing sugar is not more than 1% w/v. it is store in a cool place in tightly closed amber colored bottle protected from light and moisture. The dosage regimen is 1-2 tablespoon twice a day after meal in the form of syrup and 2 tablets twice a day after meal in the form of tablet.

### Materials and Methods

The list of ingredients used in the preparation of Dashmularishta Tablets are Shalparni (Desmodium gengeticum), Prishnparni (Uraria picta), Brihati (Solanum indicum), Kantakari (solanum xanthocarpum), Goksura (Tribulus terrestris), Bilwa (Aegle marmelos), Shyonak (Oroxylum indicum), Gambhari (Gmelina arborea), Patala (Streptosperneum sauveolens), Agnimantha (Premna integrifolia) these all above are commonly known as Dashmool and the other ingredients are Chitrak Mool, Pushkar Mool, Lodhra Tavak,Guduchi, Amlaki, Khadira, Haritaki, Kushtha, Manjishtha, Devadarav, Vidanga, Yashtimadhu, Kapitha, Vibhitaka, Punarnava, Chavya, Priyangu, Haridra, Shveta Sariva, Bharangi, Kutaja Beej, Karkat Shringi, Shati, Musta, Trivrit, Krishna Jiraka, Padmaka,

Rasna, Renuka, Puga, Shatahva, Kankola, Harivera, Shweta Chandana, Sukshmaila, Tejpatra, Tavak, Jaiphala, Lavang, Ashvagandha, Virahi, Vidari, Shatavari, Pippali, Nagkeshara, Dhanvayasa, Asana, Draksha, Dhataki.

Aerosol (colloidal silicon dioxide) is used as adsorbant, anticaking agent, glidant, tablet disintegrant, thermal stabilizer, viscosity increasing agent. Calcium carbonate acts as buffering agent, coating agent, opacifier, tablet binder and diluents. Croscarmellose sodium, Sodium starch glycolate are act as tablet superdisintegrant. Magnesium stearate acts as lubricant. Microcrystalline cellulose acts as adsorbent, binder, suspending agent and diluents. Talc is used as glidant. Instamoist shield, methylene chloride and isopropyl alcohol are used as coating materials.

**Experimental methods**

**Formulation development of conventional tablet of Dashmularishta:**

Dashmularishta Powder was prepared by using all the label claim drugs on liquid syrup.

**Selection of manufacturing processes:**

Decoction of all the herbs was prepared in the boiler. Decoction was concentrated by use of falling film evaporator. Powder from the concentrated decoction was prepared by Spray drier. Tablets were prepared by direct compression. Dashmularishta tablets each weighing 475 mg containing 325 mg of drug was formulated. Required amount of all ingredients were weighed accurately according to the formula. Ingredients were sifted through BSS # 30, further lubricated with lubricants and glidants which were sifted through BSS # 44 and thoroughly mixed for 10 min. Finally powder mixture was directly compressed into tablets using a 16 station compression machine equipped with BB tooling. Film Coating of Tablets were done using instamoist shield to protect the drug from atmospheric attack. Tablets after the preparation were packed into suitable containers and their accelerated stability studies (40◦C/75% RH) were carried out to check the stability of the product formulated.

**Table 1: Formulation of Dashmularishta Tablet and effect of concentration of binder using direct compression methods**

| **Batch number** | **B 01** | **B 02** | **B 03** |
|---|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 | 325 |
| Microcrystalline Cellulose (102) | 105 | 90 | 100 |
| Cross Carmellose Sodium | 15 | 20 | 20 |
| Talc | 15 | 7 | 10 |
| Magnesium Stearate | 15 | 8 | 10 |
| Starch | - | 15 | - |
| Aerosil | - | 10 | 10 |
| **Total** | 475 | 475 | 475 |

**Table 2: Preparation of trial batches with different diluents (Starch and Calcium Carbonate):**

| **Batch number** | **B 04** | **B 05** |
|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 |
| Microcrystalline Cellulose (102) | 70 | 70 |
| Aerosil | 28 | 28 |
| Starch | 34 | - |
| Calcium Carbonate | - | 34 |
| Talc | 4 | 4 |
| Magnesium Stearate | 4 | 4 |
| Cross Carmellose Sodium | 10 | 10 |
| **Total** | 475 | 475 |

**Table 3: Formulation of trial batches using different binders**

| Batch number | B 06 | B 07 | B 08 | B 09 |
|---|---|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 | 325 | 325 |
| Microcrystalline Cellulose (101) | 80 | - | 80 | - |
| Microcrystalline Cellulose (102) | - | 80 | | - |
| Starch | - | - | - | 80 |
| Aerosil | 15 | 15 | 15 | 15 |
| Starch Paste (7%) | 10 | - | - | - |
| Starch Paste (8%) | - | 10 | 10 | 10 |
| Calcium Carbonate | 27 | 27 | 27 | 27 |
| Talc | 4 | 4 | 4 | 4 |
| Magnesium Stearate | 4 | 4 | 4 | 4 |
| Cross Carmellose Sodium | 10 | 10 | 10 | 10 |
| **Total** | 475 | 475 | 475 | 475 |

**Table 4: Formulation of trial batches using different binders**

| Batch number | B 10 | B 11 | B 12 | B 13 | B 14 | B 15 |
|---|---|---|---|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** | **mg/tab** | **mg/tab** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 | 325 | 325 | 325 | 325 |
| Microcrystalline Cellulose (102) | 69 | 69 | 69 | 97 | 100 | 100 |
| Aerosil | 15 | 15 | 15 | 15 | 15 | 12 |
| Cross Carmellose sodium | 40 | 30 | 28 | 15 | 13 | 15 |
| Sodium starch glycolate | 10 | 20 | 30 | 15 | 13 | 13 |
| Talc | 8 | 8 | 4 | 4 | 4 | 4 |
| Magnesium Stearate | 8 | 8 | 4 | 4 | 5 | 6 |
| **Total** | 475 | 475 | 475 | 475 | 475 | 475 |

**Table 5: Effect of change in concentration of glidant and lubricant in combination with binder**

| Batch number | B 16 | B 17 | B 18 |
|---|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 | 325 |
| Microcrystalline Cellulose (102) | 96 | 88 | 85 |
| Calcium Carbonate | 10 | 9 | 12 |
| Light Magnesium Carbonate | 11.5 | 12.5 | 12 |
| Aerosil | 10 | 18 | 15.5 |
| Cross Carmellose sodium | 7.5 | 7.5 | 7.5 |
| Sodium starch glycolate | 7 | 7 | 7 |
| Talc | 3 | 4 | 5 |
| Magnesium Stearate | 5 | 4 | 6 |
| **Total** | 475 | 475 | 475 |

**Table 6: Effect of change in concentration of light Magnesium Carbonate**

| Batch number | B 19 | B 20 | B 21 | B 22 |
|---|---|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 | 325 | 325 |
| Light Magnesium Carbonate | 22 | 25 | 15 | 10 |
| Calcium Carbonate | 18 | 12.5 | 15 | 25 |
| Aerosil | 6 | 12.5 | 20 | 20 |
| Microcrystalline Cellulose (102) | 88 | 90 | 90 | 85 |
| Talc | 8 | 5 | 5 | 4 |
| Magnesium Stearate | 8 | 5 | 5 | 6 |
| **Total** | 475 | 475 | 475 | 475 |

**Table 7: Effect of change in concentration of Magnesium Carbonate**

| **Batch number** | **B 23** | **B 24** |
|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 |
| Microcrystalline Cellulose (102) | 86 | 91 |
| Aerosil | 15 | 15 |
| Cross Carmellose Sodium | 13 | 13 |
| Sodium Starch Glycolate | 13 | 13 |
| Magnesium Carbonate | 15 | 10 |
| Talc | 4 | 4 |
| Magnesium Stearate | 4 | 4 |
| **Total** | 475 | 475 |

**Table 8: Effect of change in concentration of Super Disintegrants (in same ratio)**

| **Batch number** | **B 25** | **B 26** |
|---|---|---|
| **Ingredients** | **mg/tab** | **mg/tab** |
| Drug | 325 | 325 |
| Microcrystalline Cellulose (102) | 50 | 50 |
| Calcium Carbonate | 15 | 15 |
| Aerosil | 12.5 | 12.5 |
| Cross Carmellose Sodium | 12.5 | 7.5 |
| Sodium Starch Glycolate | 12.5 | 7.5 |
| Talc | 3.5 | 3.5 |
| Magnesium Stearate | 4 | 4 |
| **Total** | 475 | 475 |

**Evaluation of conventional tablets**

**Precompression study of the granules**

**Table 5: Tapped density, Bulk density, Angle of repose, Carr's index, Hausner's ratio values of different batches blend of Dashmularishta powder**

| **Batch no.** | **Bulk Density** | **Tapped Density** | **Angle of repose (Type of flow)** | **Hausner's Ratio** | **Carr's Index** |
|---|---|---|---|---|---|
| B 01 | 0.468 | 0.632 | 31.2 (Passable) | 1.49 (Very Poor) | 35.04 (Very Poor) |
| B 02 | 0.456 | 0.629 | 47.2 (Poor) | 1.53 (Very Poor) | 37.95 (Very Poor) |
| B 03 | 0.521 | 0.623 | 40.3 (Fair) | 1.21 (Fair) | 19.97 (Fair) |
| B 04 | 0.502 | 0.643 | 38.3 (Fair) | 1.40 (Poor) | 28.08 (Poor) |
| B 05 | 0.497 | 0.610 | 37.9 (Fair) | 1.32 (Passable) | 22.73 (Passable) |
| B 06 | 0.463 | 0.662 | 35.6 (Good) | 1.63 (V. V. Poor) | 42.08 (V.V. Poor) |
| B 07 | 0.484 | 0.632 | 36.3 (Fair) | 1.39 (Poor) | 30.57 (Passable) |
| B 08 | 0.473 | 0.621 | 36.9 (Fair) | 1.44 (Poor) | 31.38 (Poor) |
| B 09 | 0.497 | 0.641 | 37.1 (Fair) | 1.37 (Poor) | 28.97 (Poor) |
| B 10 | 0.471 | 0.648 | 37.2 (Fair) | 1.38 (Poor) | 27.30 (Poor) |
| B 11 | 0.462 | 0.667 | 39.1 (Fair) | 1.44 (Poor) | 30.71 (Poor) |
| B 12 | 0.483 | 0.652 | 38.7 (Fair) | 1.35 (Poor) | 25.9 (Poor) |
| B 13 | 0.445 | 0.665 | 36.3 (Fair) | 1.34 (Passable) | 25.5 (Poor) |
| B 14 | 0.480 | 0.645 | 33.4 (Good) | 1.36 (Passable) | 26.5 (Poor) |
| B 15 | 0.495 | 0.635 | 32.1 (Good) | 1.28 (Passable) | 22.1 (Passable) |
| B 16 | 0.493 | 0.648 | 38.1 (Good) | 1.31 (Passable) | 23.90 (Passable) |
| B 17 | 0.437 | 0.655 | 34.3 (Good) | 1.34 (Passable) | 25.6 (Poor) |
| B 18 | 0.474 | 0.634 | 35.5 (Fair) | 1.33 (Passable) | 25.2(Poor) |
| B 19 | 0.484 | 0.614 | 37.1 (Fair) | 1.39 (Poor) | 26.85 (Poor) |
| B 20 | 0.487 | 0.627 | 36.8 (Fair) | 1.40 (Poor) | 28.74 (Poor) |
| B 21 | 0.493 | 0.650 | 37.6 (Fair) | 1.45 (Poor) | 31.84 (Poor) |
| B 22 | 0.489 | 0.632 | 35.9 (Fair) | 1.25 (Fair) | 22.6 (Passable) |
| B 23 | 0.495 | 0.657 | 35.6 (Fair) | 1.33 (Passable) | 24.6 (Passable) |
| B 24 | 0.490 | 0.629 | 37.8 (Fair) | 1.39 (Poor) | 28.36 (Poor) |
| B 25 | 0.493 | 0.637 | 32.5 (Good) | 1.29 (Passable) | 22.6 (Passable) |
| B 26 | 0.498 | 0.635 | 33.7 (Good) | 1.27 (Passable) | 21.5 (Passable) |

Among all the batches it was found that batches B14, B16, B25 and B26 exhibited acceptable flow properties with respect to angle of repose, Carr's index, Hausner's ratio.

**Evaluation of tablets**

Hardness, Thickness, Friability, Average weight was performed for all the batches (F1 to F18) and the data are presented in Table 6.

**Table 6: Results of evaluation of parameters of tablets from different batches**

| Batch no. | Average weight (mg) | Thickness (mm) | Friability (%) | Hardness (kp) |
|---|---|---|---|---|
| B 01 | 475.6 | 4.98 | 0.07 | 5.5 |
| B 02 | 475.9 | 4.96 | 0.04 | 5 |
| B 03 | 474.8 | 4.98 | 0.05 | 5.5 |
| B 04 | 475.3 | 4.96 | 0.03 | 5.5 |
| B 05 | 475.9 | 4.97 | 0.02 | 5.5 |
| B 06 | 475.4 | 4.95 | 0.05 | 6.5 |
| B 07 | 475.7 | 4.96 | 0.04 | 5.5 |
| B 08 | 476.3 | 4.99 | 0.02 | 3.5 |
| B 09 | 475.9 | 4.95 | 0.04 | 6.5 |
| B 10 | 476.3 | 4.97 | 0.04 | 4.5 |
| B 11 | 476.9 | 4.98 | 0.03 | 4.5 |
| B 12 | 475.7 | 4.98 | 0.06 | 4.5 |
| B 13 | 475.4 | 4.96 | 0.04 | 6 |
| B 14 | 475.1 | 4.96 | 0.05 | 6.5 |
| B 15 | 475.5 | 4.96 | 0.03 | 6.5 |
| B 16 | 476.8 | 4.95 | 0.05 | 6.5 |
| B 17 | 475.9 | 4.96 | 0.04 | 5.5 |
| B 18 | 474.3 | 4.96 | 0.05 | 5 |
| B 19 | 474.9 | 4.95 | 0.03 | 6 |
| B 20 | 474.0 | 4.95 | 0.02 | 6.5 |
| B 21 | 475.3 | 4.95 | 0.05 | 6.5 |
| B 22 | 475.9 | 4.96 | 0.04 | 6 |
| B 23 | 475.3 | 4.95 | 0.03 | 6.5 |
| B 24 | 475.6 | 4.98 | 0.04 | 7 |
| B 25 | 475.9 | 4.99 | 0.05 | 7.5 |
| B 26 | 473.3 | 4.99 | 0.03 | 7 |

The results of parameters like Hardness, Thickness, Friability, Average weight of formulated batches were found to be satisfactory.

**Summary**

Dashmularishta is a fermented liquid preparation. It is rejuvenator and revitalizer and commonly known as restorative tonic. It relives post delivery weakness. It contains not more than 10%, and not less than 5% of alcohol that is self generated in the preparation over a period of time. This syrup promotes vitality and strength. It improves milk production in women's. This is also very useful in menopause. Dashmularishta restore energy in women after delivery. This is a tonic made from different herbs. It helps in removing toxins from body and nourishes body tissues. It maintains healthy female reproductive system. It is also a curative for general weakness. It combines synergistic benefit of Dashmool with other Herbs.

Oral route of administration has received more attention in the pharmaceutical field, due to flexibility in the designing of dosage form than drug delivery design with other routes of administration. Tablet dosage form for Dashmularishta were prepared so that there should be no variability in the dose as in the liquid dosage form. The drug substance is homogeneously mixed into active excipients and other inactive ingredients.

The present study involved the preparation of Dashmularishta Tablets from liquid dosage form of the formulation with the direct compression method following a number of methods, e.g. Spray Drying and Falling Film Evaporation. Lubricated blends were characterized for physical properties like loose bulk density, tapped density, angle of repose, Carr's

index, Hausner´s ratio; all blends showed satisfactory properties. All lubricated blends were compressed into tablets using round shaped punches. Tablets were evaluated for uniformity of weight, thickness, hardness, percentage (%) friability, HPTLC, Total Phenolic Content, Total Sugar Content, Water Soluble Extractives and Alcohol Soluble Extractives. Tablets were further coated with instamoist shield, which is ready-to-use for film coating. Trial Batches were prepared using different concentration of excipients. Effect of different binders was studied and it was observed that formulation prepared with Microcrystalline Cellulose (102), showed good disintegration time profile. Tablets with different concentrations of diluent were prepared and were found that calcium carbonate acted as a best diluent in this formulation at a concentration of 3.15%. Effect on the formulation of different concentrations of glidant and lubricants were studied and gave good result in the concentration rage of 0.7- 1.0%. Effect of change in the concentration of Super disintegrants was examined and it was found that Sodium Starch Glycolate and Cross Carmellose sodium in the same ratio gives good result. Accelerated stability studies were done on the optimized batch for 3 months at a temperature of 40oC/75%RH.

**Conclusion**

Powder of the drug for trials was prepared using Spray Drying Technique followed by the concentration of decoction using Steam Jacketed Pan and Falling Film Evaporator. The physical compatibility study at 40oC/75% RH showed that Dashmularishta Powder and excipients used found to be physically compatible. HPTLC data showed that Dashmularishta Powder and excipients used were found to be compatible. Total Phenol Content data showed that Dashmularishta Powder retains its antioxidant property. Formulation was prepared with Direct Compression method. Characterization of powder used to prepare different batches of tablet dosage form was done for bulk density, tapped density, Carr's index, Hausner's ratio, Angle of repose and powder was found to have good flow and compressibility. The tablets prepared were found to be within the limits with respect to hardness, average weight, %friability and thickness. By various trial batches, it is determined that 1:1 ratio of super disintegrants was found to be best. Microcrystalline cellulose (102) was found to be the best binder in controlling the disintegration time of drug when compared with Microcrystalline Cellulose (101) and Starch. Increasing tablet hardness increases the

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