



Preparation and Evaluation of *Amavatvidhvansa rasa*- A Herbomineral Formulation

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Abstract:

In Ayurvedic system of medicine *Amavatvidhvansa rasa* is used for arthritis and other inflammatory conditions. This classical formulation is based on *Bruhatniguntu Ratnakar*. In the present study an attempt has been made to formulate *Amavatvidhvansa rasa*. The tablets were prepared by direct compression method. Prepared tablet does not disintegrated in specified time hence another four batches were prepared using super disintegrants in different ratios. Tablets were evaluated by measuring hardness, friability, weight variation and disintegration. Formulations with 2% superdisintegrants, the drug release was rapid. Stability studies were also performed. All the tablets met the pharmacopoeial requirements for all parameters tested.

Keywords: *Amavatvidhvansa rasa*, herbo-mineral, hardness, friability, weight variation

Introduction

Various ayurvedic formulations have been found to be clinically useful remedies, in a number of disorders, with advantages like better acceptance by the patient and less cost ⁽¹⁾. However, the study on drug release of many of these formulations have not been proven nor refuted by controlled studies. Present studies on ayurvedic anti-arthritic formulations are of important considerations, since anti-arthritic remedies are usually taken for long periods of time. In Ayurvedic system of medicine *Amavatvidhvansa rasa* is used for arthritis and other inflammatory conditions. The classical formula known as *Amavatvidhvansa rasa* (AVVR) is based on *Bruhatniguntu Ratnakar* ⁽²⁾ which makes use of the following ingredients to prepare the dosage form, viz: Purified mercury (*shuddha Paradā*), purified sulphur (*shuddha Ghandaka*), purified aconite (*shuddha Vatsanabhā*) and

aqueous decoction of Chitrakā (*Plumbago zeylanicum*).

The tablet is the most widely used dosage form because of its convenience in terms of self-administration, compactness, and ease in manufacturing. The oral route of drug administration is the most important method of administering drugs for systemic effects ⁽³⁾. Except in few cases, parenteral route is not routinely used for self administration of medications. The topical route of administration is limited in its ability to allow effective drug absorption for systemic drug action ^(4,5). It is probable that most of drugs used to produce systemic effects are administered by the oral route. Ayurvedic herbal formulations were also administered preferentially by oral route ⁽⁶⁾.

Material and methods

Collection and authentication

Roots of *Plumbago zeylanicum* was collected from local area of Belgaum city and *Aconitum ferox* was collected from Varanasi, U.P. and both plants were get authenticated by taxonomist Dr. Harsha Hegade, Research scientist, ICMR, Belgaum.

Chemicals:

Mercury and Sulphur were purchased from Merck lab, Mumbai. Complete Freund's Adjuvant was purchased from Sigma Aldrich, USA. anaesthetic ether (Merck Lab, Mumbai). All other chemical used are analytical grade.

Preparation of Amavatavidhvansa rasa⁽²⁾

Amavatavidhvansa rasa was prepared in the B.M.K Ayurvedic College, Belgaum by using following formula given in table 1.

Table 1: Formula for preparation of Amavatavidhvansa rasa

Ingredients in mg	F1	F2	F3	F4	F5
Shudha Parada (Purified Mercury)	68	68	68	68	68
Shudha Gandhaka (Purified Sulphur)	272	272	272	272	272
Shudha Vastanabha (Purified Aconite)	21.25	21.25	21.25	21.25	21.25
Starch glycolate	0.0	1.87	3.74	7.48	14.96
Chitraka (<i>Plumbago zeylanica</i> root) juice	q.s	q.s	q.s	q.s	q.s
Total in mg	375	375	375	375	375

Procedure

Amavatavidhvansa rasa (AVVR) was prepared in laboratory of KLEU's B.M.K Ayurvedic College, Belgaum as reported in the traditional text. Mercury so obtained was purified through sublimation. For purification of the sulphur and aconite, the traditional method using cow's milk/ghee and urine were employed. Purified mercury and sulphur were mixed in a mortar and crushed till the whole mixture was converted into a fine black, lustreless powder (*Kajjali*). This fine powder *Kajjali*, was mixed with aconite powder and juice of the root of *Plumbago zeylanica* and

triturate till to get a semisolid mass. This semisolid mass was used to prepare a vati (Tablet) of 375 mg weight.

Evaluation of Tablets⁽⁷⁻⁹⁾

The five forms of Tablets (T1, T2, T3, T4 and T5) were evaluated for general appearance, friability test, hardness test, disintegration test and dissolution test.

Thickness

Dimension of the tablets was measured by using a calibrated dial caliper. Five tablets of each formulation were picked out randomly and its thickness was measured individually.

Weight variation

Twenty tablets were selected at random and weighed individually. The individual weights were compared with the average weight for determination of weight variation. The percentage deviation was calculated and then compared with USP specifications.

Hardness

Five tablets were randomly selected from each batch and hardness of tablets was determined by using Monsanto hardness tester. The mean values and standard deviation for each batch were calculated.

Friability

Friability indicates the ability of a tablet to withstand mechanical shocks while handling. Friability of the tablets were determined using Roche Friabilator and is expressed in percentage (%). Ten tablets were initially weighed ($W_{initial}$) and placed into the friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions and then the tablets were weight again (W_{final}). The loss in tablet weight due to abrasion or fracture was the measure of tablet friability. Percent friability (f) was calculated by using the following formula.

$$f = \frac{W_{\text{initial}} - (W_{\text{final}})}{(W_{\text{initial}})} \times 100$$

In vitro disintegration time

The disintegration time for all formulations was carried out using tablet disintegration test apparatus. Six tablets were placed individually in each tube of disintegration test apparatus and discs were placed. The water was maintained at a temperature of $37 \pm 2^\circ\text{C}$ and time taken for the entire tablet to disintegrate completely was noted.

Accelerated Stability Study ⁽¹⁰⁻¹²⁾

In order to determine the change in *in-vitro* release profile on storage, stability study of batch F5 was carried out at 40°C in a humidity chamber having 75% RH. Samples were withdrawn at regular intervals during the study of 60 days. Formulation is evaluated for change in *in-vitro* drug release pattern, hardness and disintegration time.

Results and Discussion

The prepared tablets were evaluated for various parameters such as colour, average weight, hardness, friability and disintegration time, which were found to be acceptable as per Pharmacopoeial specifications. Physical parameters confirmed to the requirements such as taste, and color. The results of physicochemical evaluation of tablets are given in Table 1. As the material was semisolid, tablets were obtained of uniform weight due to uniform die filling. Weight variation was found within the specification of Indian Pharmacopoeia. Average weight of all the 5 formulation was found to be 379 mg. Hardness of tablets was between 3.3-3.9 kg/cm² for all the formulations. The thickness was found in range of 4.15- 4.23 mm. Friability of the tablet was found to

be below 1%, indicating a good mechanical resistance, it is in between 0.28-0.43%. The friability value below 1% was an indication of good mechanical resistance of the tablet.

All the prepared formulations were disintegrated within 30 minutes except F1 it was not disintegrated till 120. The *in vitro* disintegration time for all other batches of formulations ranged from 32.54 ± 1.55 min to 39.32 ± 1.21 min. Among the formulations, F4 was found to have the minimum disintegration time of 32 ± 1.55 min.

In the present study, it is observed that the disintegration time of the tablets time decreased with increase in the level of sodium starch glycolate up to 2% in the tablets. However use of 4% of sodium starch glycolate showed decrease in disintegrating time. It indicates that increase in the level of sodium starch glycolate had a positive effect on the disintegration of the tablets till 2%. Thus, tablet disintegration is retarded to some extent with tablets containing sodium starch glycolate. It was also observed that use of disintegrating agent does not affects the other parameters.

Stability studies performed on batch F4 as per ICH guidelines for 60 days at $40^\circ\text{C} \pm 2^\circ\text{C}$ / 75% RH $\pm 5\%$. That shows no remarkable changes in the physical properties of the tablets as well as no remarkable changes in the release profile as indicated in Table 2. The studies shows tablets after stability studies are in acceptable range. From results it is concluded that the formulation F4 containing 2% w/w of sodium starch glycolate was found to be promising.

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Table 2: Quantitative Evaluation of *Amavatavidhvansa rasa*

Code	Thickness (mm)	Hardness test (kg/cm ²)	Weight variation (mg)	Friability %	Disintegration time (min)
F1	4.21±0.03	3.8±0.43	379.53±1.98	0.32±0.03	>120
F2	4.17±0.05	3.3±0.34	384.54±2.04	0.35±0.04	35.76±1.23
F3	4.15±0.08	3.9±0.52	378.76±2.13	0.32±0.03	37.53 ±1.04
F4	4.23±0.04	3.7±0.25	394.66±1.89	0.28±0.02	32.54±1.55
F5	4.15±0.06	3.3±0.12	399.89±1.89	0.43±0.01	39.32±1.21

Table 3: Physical characteristics of *Amavatavidhvansa rasa* at temperature (40±2 °C/ 75% RH±5%)

Physical parameter	0 Days	15 Days	30 Days	60 Days
Hardness test	3.7±0.07	3.8±0.09	3.8±0.06	3.7±0.05
Friability	0.31±0.02	0.30±0.08	0.31±0.08	0.32±0.05
Disintegration time	32.22±1.36	32.34±1.03	33.11±1.54	32.56±1.44

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