Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 15 (2), 2024; 370-374

Preliminary Physicochemical Evaluation of *Madhumalini Vasant Ras* tablet – An Ayurveda Herbo-mineral Formulation

Research Article

Shriniwas Jadhav[1*], Asokan V[2], Mahesh S[3]

1. PhD Scholar, 2. Ph.D. Guide,
Department of PG Studies in Prasuti tantra and Stree Roga, PIA, Parul University. Gujarat. India.
1. Associate Professor, Government Ayurved College and Hospital, Nanded, Maharashtra. India.
3. Research officer, Central Ayurveda Research Institute, CCRAS, Patiala, Punjab. India.

Abstract

Introduction: As per WHO reports, 170 WHO member states have been practicing various indigenous traditional medicines. For the global reorganisation of Ayurvedic drugs advanced standardisation techniques may be involved to maintain quality assurance. *Madhumalini Vasant Ras* (MVR) is a well-known *Ayurvedic* herbo-mineral formulation used in the treatment of IUGR (Intra Uterine Growth Retardation). This formulation is not mentioned in the *Ayurveda* Formulary of India and there is no data on the quality standards of MVR available. So in this study, preliminary data on physicochemical analysis along with HPTLC evaluation of *Madhumalini vasant Ras* is generated. Aim and objective: To evaluate and generate data on the physicochemical parameters of the *MVR* tablet. Materials and Method: The raw drugs were authenticated by experts of *Dravya Guna* and *Rassastra Bhaishajya Kalpana* departments and tablets (125 mg) were prepared at the pharmacy, Parul institute of Ayurveda, Vadodara. Then the physico-chemical parameters and microbial limits were checked and HPTLC analysis was done. Results: While evaluating the physicochemical parameters, the pH value was 4.19, LOD 6.01%, Total ash value 11.54%, Acid insoluble ash 8.70%, water-soluble extractive value was 22.20% w/w, alcohol soluble extractive value was 13.40% w/w, HPTLC at 254 nm and at 366 nm showed five common spots. The Microbiological analysis shows that the formulation is free from microbes. Conclusion: Preliminary data on organoleptic characters, antimicrobial evaluation, various physicochemical parameters and HPTLC of MVR tablet is generated. These data can be used as a standard for future standardization studies.

Keywords: IUGR, *Madhumalini Vasant Ras, H*igh performance thin layer chromatography, Herbo-mineral formulations, Standardization.

Introduction

The World Health Organization (WHO) and the Government of India jointly established the WHO Global Centre for Traditional Medicine. For this global centre, an investment of USD 250 million comes from the Government of India. The new WHO centre was established at Jamnagar, Gujarat, India and this initiative will promote the potential of Traditional medicine to improve health and wellness at the global level. Approximately 170 WHO member states have been using traditional drugs as per WHO reports(1). For global recognition of *Ayurvedic* drugs advanced standardization techniques may be involved to maintain quality assurance.

Madhumalini Vasanta Ras (MVR) is a widely used herbomineral preparation that belongs to the category of *Rasaushadhi* in Ayurveda classics. This formulation is mentioned in the *Rasasastra* textbooks like classics like *Rasa Chandamshu, Rasa Tantra sara va Siddha Prayoga Samgraha* etc (2)(3). It contains *Hingula* (HgS) and herbal drugs like *Priyangu* (*Callicarpa macrophylla* Yahl.), *Sati* (*Hedychium spicatum* Buch –Ham.), *Maricha* (*Piper nigrum* Linn.) and Kukkutand Rasa (Egg yolk). *Bhavana dravyas* mentioned in *Madhumalini Vasanta Ras* are *Dadima swarasa* and *Nimbu Swarasa* (lemon juice). This popular medicine is used for various ailments like chronic fever and cough, beneficial in pregnancy with debility, anaemia, asthma, chronic respiratory problems etc. It is considered to be *Balya, Vrushya, Rasayana, Garbhavruddhikara*(4).

IUGR is defined as babies with birth weight below the tenth percentile for a given gestational age for a given population as a result of pathological restriction in their ability to growth(5). Fetal weight is determined by many factors including the capacity of the mother to supply adequate quality and quantities of substrates required for growth of the foetus. The ability of the placenta to transport these nutritional substrates to the foetus also plays an important role. The main antepartum complications of the IUGR fetus are an

*** Corresponding Author:**
Shriniwas Jadhav
Associate Professor, PhD Scholar (PIA, Parul University), Department of PG Studies in Prasuti tantra and Stree Roga, Government Ayurved College and Hospital, Nanded, Maharashtra India.
Email Id: shriniwasdjadhav@gmail.com

increased incidence of oligohydramnios, antepartum fetal distress and stillbirth. Fetal hypoxia, acidosis and a high rate of caesarean delivery are considered to be Intrapartum complications. Neonatal complications include hypoglycemia, hyperbilirubinemia, meconium aspiration, and persistent fetal circulation(6). In the Ayurvedic text, *Garbhashosha* is also stated as '*Vatabhipanna Garbha'*, it can be defined as underdevelopment or undernourishment of part or whole body of the fetus in utero(7). Safety studies of various herbo-mineral preparations are also a need for global acceptance of Ayurved(8). *Madhumalani Vasant Ras* (MVR) is one of formulations which has been used and proved in clinical practice in the management of IUGR. This formulation is not mentioned in *Ayurveda* Formulary of India and there is no published data on the quality standards of *MVR*. So in this study, preliminary data on physicochemical analysis along with HPTLC evaluation of *Madhumalini Vasant Ras* is generated.

Materials and Methods

Collection and authentication of raw materials

The ingredients of *Madhumalini Vasant Ras* (MVR) i.e. *Hingula*, *Maricha, Priyangu, Shathi*, *Kukudanda ras* and bhavana dravyas like *Nimbuka* and *Dadima swarasa* were procured from the Pharmacy, Parul Institute of Ayurveda, Vadodara. The raw drugs were authenticated by experts of *Dravya guna* and *Rasasastra Bhaishajya kalpana* departments of Parul Institute of Ayurveda, Baroda as per the classical *grahya lakshana* and standards mentioned in Ayurveda Pharmacopeia of India (API). The ingredients and the part used are given in Table 1.

Table No. 1: Ingredients of *Madhumalini Vasant Ras* (MVR)(3)

Ingredients	B.N.	Parts used	Quantity used
Hingula	Cinnabar (HgS)	-	200 g
Kukudanta ras	Egg yolk	-	200 g
Marich	*Piper nigrum* Linn.	Fruit	100 g
Priyangu	*Callicarpa macrophylla* Yahl.	Inflorescence	100 g
Shathi	*Hedychium spicat um* Buch –Ham.	Tuber	100 g
Nimbuka	*Citrus medica* L.	Fruit	Quantity sufficient
Dadima	*Punica granatum* Linn.	Fruit	Quantity sufficient

Method of preparation

MVR formulation is prepared as per the reference of *Rasa chandamshu.* Raw drugs like *Maricha, Priyangu, Sati* were cleaned, dried, powdered, and passed through sieve number #85 and stored in air tight containers. *Ashodita hingula* was powdered and seven times *bhavana* was done with *dadima swarasa*. This *Hingula* was mixed with equal quantity of egg yolk and heated in an iron vessel in *mandagni* (mild heat) till it attained powder form. The processed *Hingula* was weighted and added half the quantity of powdered *Maricha, Priyangu, Shathi* and triturated well. *Nimbuka swarasa* was used for *Bhavana* procedure for 7 times. The final product is dried in the shade and mixed with the binding agent (Gum Acacia 5 %) (9). Then, the mixture was converted into granules with the help of the granulator machine and tablets (125 mg) were made using Tablet-making machine at the pharmacy, Parul institute of Ayurveda, Vadodara. Packaging was done under aseptic precautions and stored properly.

Characterisation techniques used for analysis

The physicochemical characterisation of the samples of test drug MVR tablet was carried out at the analytical laboratory of Pharmacy of PIA, Vadodara. The samples of test drug were evaluated with various physico-chemical parameters like tablet hardness, Tablet friability, lowest percentage of tablet, tablet hardness, tablet friability, disintegration time, pH, loss on drying (LOD), Total ash, Acid insoluble ash, water soluble extractive and alcohol soluble extractive values and the tests were carried out at R& D centre, VASU Pharmacy, Vadodara(10). Microbiological study was also conducted at R& D centre, VASU Pharmacy, Vadodara for the sample of *Madhumalini vasant Ras* tablet.

High-performance thin layer chromatography(11)

HPTLC was carried out at R& D centre, VASU Pharmacy, Vadodara. Test solution was prepared by weighing 1 gm of sample in an iodine flask and 20 ml methanol is added. Then reflux for 15 minutes and filter with the help of Whatman filter paper no.1. Spray reagent was prepared by mixing 0.5ml Anisaldehyde with 10 ml Glacial acetic acid followed by 85 ml Methanol and 5 ml Sulphuric acid (85%).It was carried out with methanolic extract of *MMV* on precoated silica gel 60 F-254 aluminium plate as 5 mm bands, 10 mm apart, and 80 cm from the edge of the plates, by means of a CAMAG Linomat 5 sample applicator (Sample application volume 8 µl). The mobile phase used was Toluene: Ethyl acetate: acetic acid (7:2:1 V/V). The plates were developed in CAMAG twin trough chamber (20 cm × 10 cm) and spots were detected in short U. V. (254 nm) and long U. V (366 nm), followed by photo documentation. The retention factor was calculated using the formula

Rf = Distance travelled by solute/Distance travelled by solvent.

Microbial limit test

The sample of MVR tablet was sent for microbiological analysis at Research and Development centre, VASU pharmacy, Vadodara. The microbial limit test was carried out as per the reference mentioned in Ayurvedic Pharmacopoeia of India (12). It included total bacterial count, total fungal count, and presence of pathogens like Escherichia coli, Salmonella sp., Pseudomonas aeruginosa, and Staphylococcus aureus.

Observation and Results

Since this is a preliminary physicochemical analytical study only one pilot batch of MMR is prepared. MVR was prepared by maintaining all quality standards and tablets (125 mg) were made using Tablet making machine at the pharmacy, Parul institute of Ayurveda, Vadodara.

Organoleptic evaluation

Since this is a preliminary physicochemical analytical study only one pilot batch of MMR is prepared.

Table 2 : Results of organoleptic evaluation of MVR tablets

S.N.	Parameters	Result
1	Odour	Slightly aromatic
2	Colour	Brick red coloured tablet
3	Taste	Characteristic
4	Consistency	Tablet form (solid)

Physicochemical parameters of MMV tablet

The observations of various physicochemical analysis were presented in Table no.3.

Table 3: Results of Physicochemical evaluation of MVR tablets

S.N.	Parameters	Result
1	pH	4.19
2	Loss on drying	3.01%
3	Total ash	11.54%
4	Acid insoluble ash	8.70%
5	Water soluble extractive	22.20%
6	Alcohol soluble extractive	13.40%
7	Average tablet weight	125 ± 10 mg
8	Highest weight	135 mg
9	Lowest weight	115 mg
10	Hardness	1.5 kg/cm^3
11	Friability	0 % w/w
12	Disintegration time	14.30 minutes

High-performance thin-layer chromatography

HPTLC analysis of sample of MVR tablet was carried out and the data was arranged in table 7. HPTLC evaluation revealed five common spots in 254 and 366 nm (Table 4 and Figure 1(a), 1(b)).

Table 4: Results of HPTLC of sample of MVR tablet

Name of drug	254 nm		366 nm	
	No. of spots	Rf Value	No. of spots	Rf Value
Madhumalini Vasant Ras	9 spots	0.11, 0.30, 0.35, 0.58, 0.62, 0.67, 0.72, 0.75, 087	5 spots	0.58, 0.62, 0.67, 0.72, 0.75

*Rf- Retention factor

Figure 1 (a): HPTLC chromatogram of MVR @ 254 nm

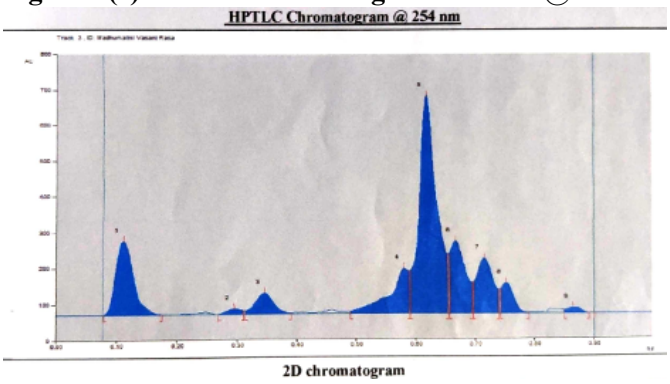
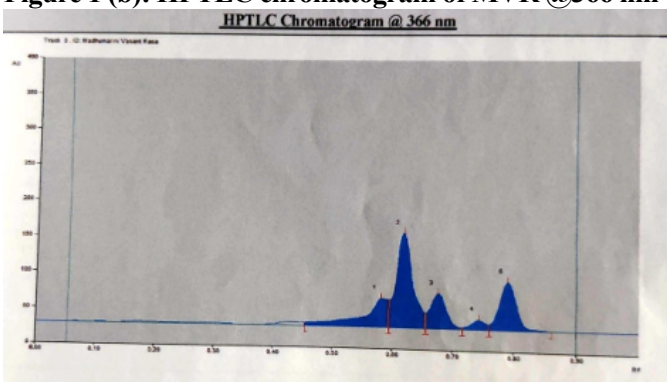


Figure 1 (b): HPTLC chromatogram of MVR @366 nm



Microbiological analysis

The values of microbial limit test of *MVR* was found within API limit with total microbial plate count, Yeast and moulds counts. The various bacteria's like. Salmonella, Pseudomonas, Staphylococcus and E. coli were found to be absent in the sample.

Table 5: Results of Microbiological analysis of MVR tablet

S.N.	Microbial test		Permissible limit as per API
1	Total Microbial plate count (TPC)	Below API limit	10^5 cfu/g
2	Total yeast and mould count (TYMC)	Below API limit	10^3 cfu/g
3	Staphylococcus aureus	Absent	Absent
4	Salmonella sp.	Absent	Absent
5	Pseudomonas aeruginosa	Absent	Absent
6	Escherichia coli	Absent	Absent

* cfu/g: colony forming unit per gram

Discussion

In the study, *MVR* has been prepared as per the reference of *Rasa Chandamshu.* In *Madhumalini Vasanta Rasa, bhavana dravyas* like *Dadima swarasa* and *Nimbu swarasa* is used. These two *bhavana dravyas* are having abundance of nutrients and antioxidants. *Kukundanda ras* is not a common ingredient in Ayurveda formulations, but in MVR it is used to by mixing it with *shodhita hingula* and heated

in mild fire. Eggs are a good source of essential mineral such as Calcium, iron, phosphrous, zinc, vitamins and iodine (13, 14). The brick red colour of the tablet is due to the presence of *hingula* and the slightly aromatic smell may be due to *bhavana dravya nimbu*. While analysing the physicochemical parameters of tablet, shows the uniformity of weight. The average weight was 125 ± 10 mg. The higher ash value of 11.54 % and acid insoluble value indicates the presence of inorganic ingredients (like HgS) in the formulation. The higher value of water soluble extractive indicates the presence of herbal drugs and solubility of the formulation. pH of *MVR* tablet is 4.19 [Table 3], it means the tablet has acidic nature which may be due to the presence of the *bhavana dravya Nimbuka,* which is acidic in nature(15-19).

HPTLC analysis of MVR tablet was evaluated under 254 and 366 nm wavelengths. This showed. It 9 spots in 254 nm and 5spots in 366 and 5 spots were common in both wavelengths (0.58, 0.62, 0.67, 0.72, 0.75). The spots found in the HPTLC indicate the presence of phytochemicals in the formulation, which can be compared to the standards of raw drugs available. This can be used as a standard for future researches. The values of microbial limit test of MVR were found within API limit with total microbial plate count, Yeast and moulds counts. The various bacteria's like. Pseudomonas, Staphylococcus, Salmonella sp., and E. coli were not found in the sample. This shows the quality of the raw materials used and stability, quality and safety of final product(20-21).

Limitation of the study

This study was conducted only to generate the preliminary quality control data of *Madhumalini vasanta ras*. For future standardization studies minimum three batches of MVR has to be prepared and analytical parameters should be evaluated.

Conclusion

Madhumalini vasant Ras is a widely used herbomineral preparation in IUGR, mentioned in textbooks like Rasa Chandanshu. The formulation is not mentioned in Ayurveda Formulary of Indi and the quality stdandards are not yet available. This study was intended to generate a preliminary data on organoleptic and physio-chemical parameters. The Physico-chemical analysis help to generate a preliminary standard analytical profile for MVR as there is no standard available in the pharmacopoeia. This preliminary data can be used as a standard for the identity and purity of the herbomineral formulation *Madhumalini vasant ras* for future studies.

Financial support and sponsorship: Nil
Conflicts of interest: There are no conflicts of interest.

References

1. https://www.who.int/news/item/25-03-2022-who-establishes-the-global-centre-for-traditional-medicine-in-india (assessed on 10.07.2023 at 10.07)
2. Rasa tantra sara va siddha prayoga samgraha, Prathama Khanda Kharleeya Rasayana 12th edition 1980 published by Krishna Gopala Ayurveda Bhavan, pg no 367.
3. Savarikar S S, translator. Rasa Chandanshu, 1sted. New Delhi: Kendriya Ayurved Vignan Anusandhan Parishad; 2011. P 302
4. Rakesh Ganvir et al: Critical Review on Madhumalini Vasanta; A Kharaliya-Rasayana. International Ayurvedic Medical Journal {online} 2019 {cited January, 2020} Available from: http://www.iamj.in/posts/images/upload/2659_2663.pdf
5. Dutta DC's Textbook of obstetrics, edited by Hiralal Konar, published by Jaypee brothers' Medical publishers (P) Ltd, 9th edition, chapter 32, pp no. 431.
6. Gogate S (2001), Int. J. Dia. Dev. C, Fetal medicine clinic, vol.21, P.N. 51-55.
7. Ashtanga Hridayam of shrimadvagbhata edited with Sarvanga Sundara of Arundatta and Ayurvedarasayana of Hemadri commentary edited by Pt.bhisagacharya Harishastri Paradkar Vaidya, Published by Chaukhamba Krishnadas Academy edition 2009, chikitsa Sthana chapter 21, verse 21, pp.724
8. Mahesh, S., Chaudhary, S. Y., Nariya, M., & Patgiri, B. J. (2021). Acute and Chronic Toxicity Study of Vatavidhvamsana Rasa, an Ayurvedic Herbomineral Formulation. *Toxicology International*, *28*(4), 421–433. https://doi.org/10.18311/ti/2021/v28i4/28118.
9. Arun Raj GR, Dr. Swapnil Raskar Formulation and standardization of Patoladi tablet – A polyherbal ayurvedic drug to combat Chronic Tonsillitis in children, IJBPAS, 2022, 11(8): 3667-3678
10. Lohar DR. Protocol for Testing Ayurvedic, Siddha and Unani Medicines, Government of India Department of AYUSH. Ghaziabad: Ministry of Health and Family Welfare, Pharmacopoeial Laboratory for Indian Medicines;2016. 21p.
11. Reich E, Schibii A; High Performance- Thin Layer Chromatography for the analysis of medicinal plants. Germany: Thieme medical publishers. Inc. 2007; p.129-60.
12. The Ayurvedic Pharmacopoeia of India I (I-VII), Govt of India, Ministry of Health and Family Welfare, Department of ISM & H New Delhi, 2000, 207.
13. Jadhav S, Asokan V, Bhagyalaxmi. Role Of Madhumalini Vasant Rasa On Garbhashosha (Fetal Growth Restriction) - A Case Report IJBPAS, 2022, 11(3): 126-130.
14. Sujata Kadam, Randomised, Standard Control Clinical Trial -To Study The efficacy Of *Madhumalinivasant* On *Upavishtak, IAMJ: 2014,2(3),301-06*
15. Mahesh S, Patgiri BJ. Praveen Kumar KS. Pharmaceutico-analytical study of *Vatavidhvamsana Rasa*. International Journal of Ayurvedic Medicine. 2020; 11(2):235–40. https://doi.org/10.47552/ijam. v11i2.1446

16. T S, R. C., R, M., & B, V. (2021). A Preliminary Pharmacognostical and Physico Chemical Assay of Shalmali moola Granules. *International Journal of Ayurvedic Medicine*, *12*(2), 314–317. https://doi.org/10.47552/ijam.v12i3.1883
17. Swathy Vijayakumar, Mahadevan Subramaniam, Vandana Rani Madhavan, Anusree Dileep, Ramesh Narve Venkatesha, & Delvin Thozhuthumparambil Robin. (2021). Preliminary Physico-Chemical Profile of Yashtimadhu Ghrita. International Journal of Research in Pharmaceutical Sciences, 12(3), 2184–2189.
18. Vaidya VN, Tatiya AU, Elango A, Kukkupuni SK, Vishnuprasad CN. Need for comprehensive standardisation strategies for marketed Ayurveda formulation. J. Ayurveda Integr Med. 2018; 9; 312-315
19. Ila Tanna,S. M. S. Samarakoon,H. M. Chandola,V. J. Shukla.Physico-chemical analysis of a Herbo-mineral compound Mehamudgara vati – A pilot study. Ayu journal.2011;32(4);572-575.
20. Mukhi S, Bose A, Panda P, Rao MM. Pharmacognostic, physicochemical and chromatographic characterization of Samasharkara Churna. J Ayurveda Integr Med. 2016 Apr-Jun;7(2):88-99. doi: 10.1016/j.jaim.2015.11.004. Epub 2016 Jul 22. PMID: 27460817; PMCID: PMC4969313.
21. Jawanjal PM, Bedarkar PB, Patgiri BJ, Savrikar SS. Preliminary analytical study of *Bhallatakadi kshara* (herbomineral preparation). Int J Ayurveda Res 2023;4:48-53.

*****