IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

"Standardization Of Divya Vishtindukadi Vati" With Reference To Marker Compound

Author: Satyajit S. Patil*, Dr. Kiran A. Wadkar, Pradnya Wadekar, Anil A. Danane,

Pratiksha V. Gore

College Name: Appasaheb Birnale College of Pharmacy, Sangli.

Adress: South Shivajinagar, Nishant Colony, Sangli Miraj Kupwad, Maharashtra, 416416

Abstract:

Vati is a commonly used traditional medicinal formulation in Ayurveda, an ancient system of medicine that has been practiced for thousands of years in India. Vatis are herbal pills or tablets prepared using a combination of herbs, minerals, and other natural ingredients, and they play a crucial role in Ayurvedic therapeutics. However, the lack of standardized manufacturing processes and quality control measures has led to significant variations in the composition and efficacy of Vati products available in the market. These abstract highlights the importance of standardization in the production of Vati and outlines the key aspects of this standardization process. Standardization involves defining and maintaining consistent quality and efficacy parameters for Vati formulations to ensure their safety and effectiveness. **Keywords**: Standardization, Vati, Ayurveda, marker compound **Introduction:**

The standardization of Vati, an essential component of traditional Ayurvedic medicine, is critical to ensuring its safety, efficacy, and quality. Vati refers to a class of herbal preparations that are widely used in Ayurveda for various therapeutic purposes. These preparations are typically composed of a combination of herbs, minerals, and other natural ingredients carefully chosen for their healing properties.[1] The need for standardization arises from the increasing popularity of Ayurvedic remedies worldwide and the growing demand for products that can be trusted for their quality and consistency. In the past, the lack of standardized manufacturing practices has led to variations in the quality and effectiveness of Vati preparations, raising concerns about safety and efficacy. the standardization of Vati is a crucial step toward ensuring that Ayurvedic medicines can be relied upon for their therapeutic benefits while respecting the rich heritage and wisdom of traditional Ayurvedic knowledge. This endeavor not only safeguards consumer health but also contributes to the preservation and promotion of Ayurveda as a valuable healthcare system.[2]

This paper explores the significance of standardization in the context of Vati formulations, highlighting its importance in guaranteeing product quality, safety, and effectiveness. It also delves into the challenges and complexities involved in the standardization process, considering the rich diversity of Ayurvedic ingredients and traditional knowledge systems.

Divya Vishtindukadi vati:

Divya Vishtindukadi Vati is an excellent herbal medication to maintain regular nervous system function. It is an excellent natural treatment for stomach pain. This is a simple and organic medicine with no adverse effects. It stimulates the neurological system and provides immediate relief from acute nerve pain.[3]

Divya Vishtindukadi Vati is the polyherbal formulation, consisting of 4 ingredients of plant origin of which Shuddha kuchila is an important major constituent. The 250 mg of Divya Vishatindukadi vati contain 196.85 mg of Shuddha kuchila. The marker compound brucine is present in Shuddha kuchila.

Table No.1: Content in Divya Vishtindukadi Vati

Sr.no	Content	Quantity (mg)
1	Shuddha kuchila (Strychnos nux-vomica)	196.85 mg
2	Supari (Areca catechu)	19.86 mg
3	Kali Mirch (Piper Nigrum)	17.71 mg
4	Imli (Tamarindus indica)	15.74 mg

Materials and methods:

Procurement of marketed formulation:

Divya Vishtindukadi vati was procured from the local ayurvedic shop. This vati used for standardization with the help of various parameters.

Organoleptic evaluation:

It means assessing the formulation based on its colour, odour, taste, texture, etc. The method laid out by Siddiqui et al. was employed to evaluate the macroscopic study of the materials.[4] **Weight variation test:**

20 tablets were taken, and each one was weighed. Using a digital weight balance, the weight of each tablet was determined and compared to the average.[5] **Disintegration time:**

Disintegration assembly tubes are filled with six tablets. Jar has 2.5 litres of water in it.

37 ±2 °C was kept steady. Keep track of the time and average value when tablets totally crumble.[6]

Hardness test:

The hardness of the tablets was assessed using a Monsanto hardness tester. 5 pills were randomly chosen from each batch and tested.[7]

Friability test:

The friability of the tablets was assessed using the Roche friabilator. 10 pills were chosen at random from each batch and put into the friabilator. Compare the weight of the tablets after 100 rotations to before the surgery and assess their friability.[8]

Determination of Ash values: [9] Total ash:

A small sample of the ground, air-dried material, between 2-4g was obtained and precisely weighed. Material was put into the crucible, which was heated to 500–600 °C. After the operation was finished, the ash was collected, precisely weighed, and the value of the ash was determined.

% ASH = ((ashes wt.) - (crucible wt.)) x 100/((crucible and sample wt.) - (crucible wt.) **Acid Insoluble ash:**

25 ml of 0.1N hydrochloric acid was added to 1 g of ash, which was then cooked on a hot plate for 5 minutes. Wash it three times in 25 ml of water after filtering the insoluble material. Collect and precisely weigh any dried insoluble material. Calculate the acid insoluble ash based on the readings.

Acid insoluble ash (gm) = (Mass of crucible plus ash – Mass of crucible / Mass of sample) x 100 **Water soluble ash:**

25ml of distilled water was used to boil the ash for 5 minutes. On ashless filter paper, residue was collected, lit, and weighed. Calculating the percentage of water-soluble ash using the airdried medication as a reference.

Determination of extractive values: [9]

Determination of alcohol soluble extractive values:

In a closed flask, 5 g of the air-dried medication was macerated for 24 hours with 100 ml of ethanol, agitated repeatedly for 6 hours, and then left to stand for 18 hours. Quickly filtered while taking steps to prevent solvent loss, 25 ml of the filtrate was evaporated to dryness in a flat, deep dish covered in tar, dried at 105°, and then weighed. with reference to the air-dried medication, the proportion of alcohol-soluble extractive was computed.

Determination of Water soluble extractive value: employing water instead of ethanol as suggested to proceed with the determination of the alcohol soluble extractive.

Extraction, isolation and chromatographic evaluation of Divya Vishtindukadi vati:

Extraction of Divya Vishtindukadi Vati:

At a 45–50 °C temperature for 48 hours, 100 g of the powdered Divya Vishtindukadi Vati substance was extracted with 250 ml of chloroform in a Soxhlet extractor. Using a rotating evaporator, which reduces large solutions to small amounts without impacting at temperatures that vary from 30 to 40°C, the extracted substance was then concentrated under less pressure.

Isolation process for Brucine: [10]

Divya Vishtindukadi Vati powder was taken and precisely weighed. Allowed the powder to dry for 12 hr after moistening with 10% aqueous calcium hydroxide solution. Extract the airdried powder with chloroform in a Soxhlet extractor for 4 hrs. extract of chloroform filtered. The chloroform solution was extracted by using 5 volumes of 5% aqueous H2SO4. To make pH basic, mix in the 10% aqueous NaOH solution. Allowed to cool at room temperature and 50% alcohol was added to cool the mixture. The strychnine crystals observed were filtered and dried. The remaining Filtrate was used to isolate brucine. After evaporating the filtrate brucine residue was obtained. That residue is treated with dil. H2SO4 and concentrated. This product was kept overnight in the refrigerator. Then, 10 ml water and activated charcoal were added and refluxed for 1 hr., and brucine crystals were obtained, filtered, and dried.

Identification tests for isolated Brucine: [11]

Isolated brucine was subjected to qualitative test and melting point were determined and compared with standard marker compound Brucine.

UV spectroscopy:

Preparation of stock solution of standard brucine and their solution:

10 mg of standard brucine, which was precisely weighed was transferred to a 100 ml volumetric flask, in the appropriate amount of methanol, and then subjected to a 15-minute sonication process before being diluted with additional 100.0 ml of methanol.up to 10ml in volumetric flask with methanol to yield a concentration of 2µg/ml likewise 0.4 ml of stock solution in 10 ml of methanol and 1.0 ml of stock solution in 10 ml of methanol to yield a concentration 4µg/ml, 6µg/ml, 8ug/ml and 10ug/ml.

To obtain the standard brucine's maximum absorption, the produced dilutions of the substance were scanned individually in the wavelength range of 200–400 nm against methanol as a blank. Additionally, the same process was used to prepare stock solution of isolated brucine and their dilutions.

HPTLC method development for Brucine:

CAMAG HPTLC system was used to a develop method which consist of, Linomat 5 automatic TLC sample applicator, Server DESKTOP-TAG8IAQ, (version 3.2.22308.1) software was used. Merck plates with HPTLC silica gel 60 F_{254} on aluminium sheets. Initial tests were performed on TLC plates in saturated chambers to choose an appropriate mobile phase. Numerous mobile phase compositions in various ratios were tested for the fascination of choosing the mobile phase, but the resolution was not found to be adequate. Finally, Chloroform: Ethyl acetate: Diethyl amine (6:3:1v/v/v) was found to give better resolution.

Standard Preparation：

For Brucine stock solution, 400 µg/ml were prepared by dissolving accurately weighed 10 mg in chloroform to in volumetric flask 25 ml. Transfer 1ml of stock solution separately to volumetric flask 10 ml and make up the volume to 10 ml in volumetric flask with chloroform and make up volume upto 10 ml yields concentration 100µg/ml

Sample preparation:

An isolated brucine stock solution of, 400 µg/ml was made by dissolving weighed 10 mg isolated brucine in chloroform and making up 25 ml of the volume to in volumetric flask. Transfer 1ml of stock solution separately to volumetric flask of 10 ml and made volume 10 ml.

Result and Discussions:

Organoleptic evaluation:

Sample	Colour	Odour	Taste
Divya Vishtindukadi Vati	Brown	Aromatic	Bitter

Results of evaluation parameters:

Sample	Readings taken (n*=3)			Mean	±SD	%RSD
%weight variation	4%	3%	2%	3%(%w/w)	1	33.33
Hardness (Kg/cm^2)	5	5	4.7	4.90 (Kg/cm^2)	0.17325	3.5347
Friability (%)	6%	6%	7%	6.3%	0.5773	9.1160
Disintegration time(min)	44	45	44	44.33 min	0.5753	1.3022

Results of ash values:

Sample	% w/w	±SD	%RSD
Total ash	32.5%	0.013852	2.4372
Acid insoluble ash	18%	1.4314	5.555
Water soluble ash	8.5%	0.0057	3.4641

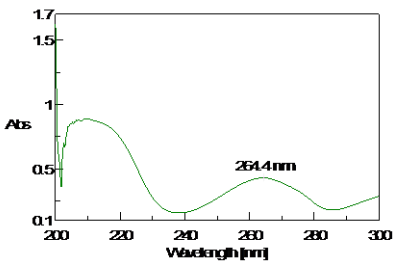
Results of extractive values:

Sample	% w/w	±SD	%RSD
Water soluble extractive value	7.4%	0.015	4.055
Alcohol soluble extractive value	17%	0.01	1.1764

Identification tests for isolated brucine:

Test	Observation	Inference
Determination of melting point:		
Melting point (Literature M.P. 178^{o}C)	175-179^{0}C	Brucine might be present
Qualitative test for brucine		
1-2 ml extract + conc. HNO_3	Yellow to orange colour appears	Brucine is present

UV spectroscopy:



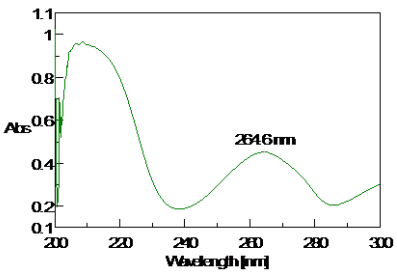


Figure 1: UV spectra for standard Brucine

Figure 2: UV spectra of isolated Brucine

The UV spectrum of standard and isolated Marker compound Brucine showed maximum absorption at wavelength 264.4nm

HPTLC method development for Brucine:

The solvent system of Chloroform : Ethyl Acetate : Diethylamine (6 : 3 : 1 v/v/v) was found to be ideal mobile phase for Brucine. Brucine isolated from Divya Vishtindukadi Vati showed one peak in HPTLC Chromatogram with Rf 0.46. standard Brucine shows peak at HPTLC chromatogram with Rf 0.47. Both isolated and standard brucine show similar peak with similar Rf value. Therefore isolated brucine from Divya Vishtindukadi Vati found similar with that standard Brucine.

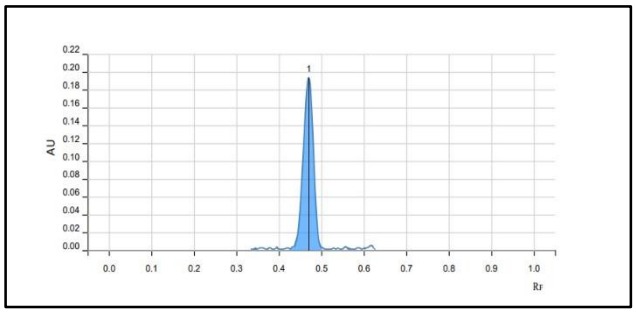


Figure 3: chromatogram of isolated Brucine

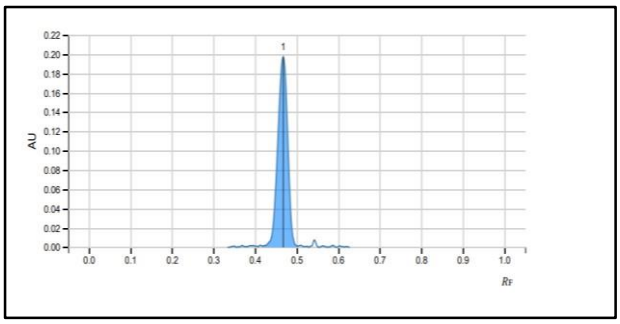


Figure 4: chromatogram of std. Brucine

Calibration curve of Brucine:

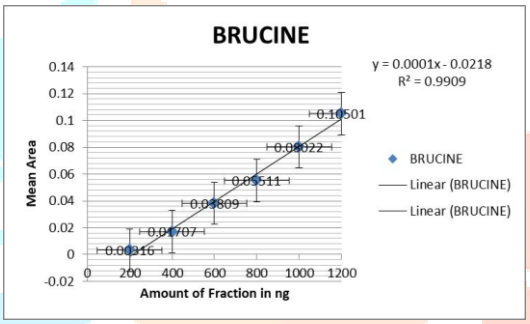


Figure 5: Calibration curve showing linearity of Standard brucine

Regression equation data of standard Brucine:

Linearity range (ng/spot)	200-1000 ng
Regression equation (Y=mX+C)	Y= 0.0001x-0.0218
Correlation Coefficient r^2	0.9909
Slope (S)	0.0001
Intercept	0.0218
Mean standard deviation of responses (σ)	0.152752
LOD	0.069 µg/ml
LOQ	0.231 µg/ml

Interday precision study for Brucine:

Sample volume in µl	Time interval (hr)	Amount fraction in ng	Mean Rf value	Mean area	±SD	%RSD
2	2	200	0.53	0.028553	0.005774	1.082532
4	2	400	0.51	0.06164	0.004714	0.912396
6	2	600	0.52	0.055573	0.01154	0.900773

Intrday precision study for Brucine:

Sample volume in µl	Time l interva (hr)	Amount fraction in ng	Mean Rf value	Mean area	±SD	%RSD
2	2	200	0.53	0.019373	0.005774	1.075808
4	2	400	0.51	0.080243	0.005774	1.117452
6	2	600	0.52	0.06238	0.01154	2.192469

Recovery study: The results of recovery study indicates that the percentage of brucine was found within the range 98.51-98.61 % w/w and the mean percentage recovery found to be
98.54%

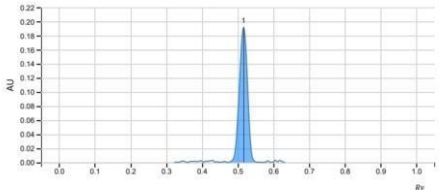


Figure 6: Densitogram of Brucine

References:

1. Nainwal P, Pharmacovigilance of herbal medicines: an intangible approach, IJPSR. 2010; 1(11):60-65.

2. Kokate CK et al. Practical Pharmacognosy, Pune, Nirali Prakashan, 46th edition, 1994, 153

3. https://www.patanjaliayurved.net/product/ayurvedic-medicine/vati/divya-vishtindukadivati/213

4. Siddiqui, Hakim MA. Format for the pharmacopeial analytical standards of compound formulation, workshop on standardization of Unani drugs, (appendix), 24-25 January. New Delhi: Central Council for Research in Unani Medicine (CCRUM); 1995.

5. https://shms-prod.s3.amazonaws.com/media/editor/147459/L5_Tablets_Evaluation.pdf

6.https://copharm.uobaghdad.edu.iq/wpcontent/uploads/sites/6/uploads/2017/lectuer/5th%20s tage/industrial/quality-control-tablet%20(1).pdf

7. https://www.slideshare.net/SarangDalvi/quality-control-tests-of-tablet

8. https://pharmastate.academy/friability-test/

9. The Ayurvedic Pharmacopoeia of India. Government of India, Ministry of Health and Family Welfare, New Delhi. The controller of publications civil lines 1999; Part 2, Vol 1, 1" edition, Appendix 2, 140-141.

10.Khadbadi S.S. et. al. Experimental Phyto pharmacognosy, Nirali prakashan,2019, page no. 5.1-5.22

11. https://www.studocu.com/en-us/document/drexel-university/foundations-of-phytotherapyclinical-applications-of-herbal/extraction-of-strychnine-and-brucine-alkaloids-from-seeds-ofnux-vomica-and-performance-of-chemical-identification-tests-for-them/41180053