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Research Article

Dadrughni Vati

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Standardization and Quality Assurance of Dadrughni Vati (Lepa) and Dadrughna Malahara: A Critical Quality Control Evaluation

Joshi SB[1*], Umretia B[2], Kalsariya BD[3]

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[1*] Shruti B Joshi, Post Graduate Scholar, Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat, India.

[2] Bharti Umretia, Reader and HOD, Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat, India.

[3] Bharat D Kalsariya, Professor and Principal, Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat, India.

Introduction: Ayurvedic formulations, such as Dadrughni Vati (Lepa) (DL) and Dadrughna Malahara (DM), are used for skin care and treatment. Understanding the physicochemical properties of these formulations is essential to assess their quality, efficacy, and stability. This study aims to evaluate and compare the key physicochemical parameters of DL and DM, focusing on pH, loss on drying (LOD), ash values, extractive properties, and other physical attributes.

Methods: The physicochemical analysis of DL and DM was performed using standard analytical procedures. pH was measured using a pH meter; LOD was determined by heating the samples; ash values, including acid-insoluble ash, were quantified through combustion; and water-soluble and alcohol-soluble extractive values were assessed using solvent extraction techniques. Additional physical tests included measuring the specific gravity, acid value, saponification value, iodine value, viscosity, and spreadability.

Results: DL exhibited a pH of 3.92, an LOD of 14.08%, and an ash value of 19.58%. Its water-soluble extractive value was 44.12%, and alcohol-soluble extractives were 13.97%. The average hardness was 9.8, and the weight was 3651 mg. DM showed a specific gravity of 0.930, an acid value of 2.22, a saponification value of 118.57, and an iodine value of 77.11. The viscosity and spreadability of DM were 15,64,333 cp and 657.95 g, respectively.

Discussion: The physicochemical properties of DL and DM indicate that both formulations are stable, genuine, and suitable for skin application. DL's pH and extractive values suggest it is moisturizing and mild, making it beneficial for conditions like Dadru, while DM's specific gravity and emulsifying properties confirm its potential for use as an effective Malahara (skin ointment). The consistency of all parameters across batches further supports the formulation's reproducibility and quality. These results underscore the therapeutic potential of DL and DM in Ayurvedic dermatological care.

Keywords: Physicochemical analysis, Ayurvedic formulations, skin care, Dadrughni Vati, Dadrughna Malahara

Corresponding Author

Shruti B Joshi, Post Graduate Scholar, Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat, India.
Email: joshishruti1110@gmail.com

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Introduction

Pharmaceutical efficacy evaluation depends critically on clinical trials and analytical studies. Analytical chemistry is integral to this process, involving the qualitative and quantitative assessment of substances to ensure that pharmaceutical products are standardized, high-quality and safe.**[1]**

Various analytical techniques examine drugs to uncover essential details about their chemical composition and Physicochemical characteristics. These assessments are vital for determining thefinished product's quality and safety profiles based on scientific data.

The advancement of scientific instruments and methodologies has greatly improved the creation of detailed databases for raw materials and finished pharmaceutical products.

This development underpins the scientific validation of the efficacy and safety of Ayurvedic medicines and facilitates their acceptance in global markets. The present analytical study was planned to develop an analytical profile for *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara*.

In this phase of the study, different samples of the raw materials and finished products of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* were evaluated by organoleptic characteristics and physicochemical analysis.

Materials and Methods

Procurement of the raw materials: *Tankana, Sphatika* and *Tila Taila* were procured from the Government Ayurved Pharmacy, Rajpipla, Gujarat. *Gandhaka, Sarjarasa, Chakramarda Beeja, Siktha, Go-ghrita* and *Go-dugdha* were procured from the local traders of Vadodara, Gujarat.*Jambiri Nimbu* was procured from the farmer of Amreli, Gujarat.

Identification of raw material: The samples of *Chakramarda* (*Cassia tora* Linn), *Sarjarasa* (*Shorea robusta* Gaertn), and *Jambiri Nimbu (Citrus jambhiri* Lush.) were identified in the Pharmacognosy Laboratory, Upgraded Department of Dravyaguna, Government Ayurveda College, Vadodara, Gujarat. The samples of *Gandhaka*, *Sphatika*, and *Tankana* were identified at the Quality Testing Laboratory of the Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurveda College, Vadodara, Gujarat. *fssai* (Food Safety and Standards Authority of India) standard *Tila Taila, Go-ghrita* and *Go-dugdha* were procured.

Preparation of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara:* All the batches of *Dadrughni Vati* (*Lepa*) were prepared as per the reference of Bheshaj Samhita**[2]** and *Dadrughna Malahara* was a modified dosage form of *Dadrughni Vati* (*Lepa*) prepared in the Pharmaceutical Laboratory of Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat.

Place of Analytical study: Quality Testing Laboratory of the Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat and Vasu Research Centre, Division of Vasu Healthcare PVT. LTD. Vadodara, Gujarat.

Organoleptic characters: The Organoleptic characters i.e., colour, appearance, odour, taste and texture of the samples were observed by sensory observations. The samples were carried out to confirm the identification of raw material as well as finished products by organoleptic characters.

Physico-chemical parameters: Physicochemical parameters were analyzed according to the Ayurvedic pharmacopeia of India (API).

Preliminary analysis carried out were pH value,**[3]** loss on drying,**[4]** water soluble extractive,**[5]** alcohol soluble extractive,**[6]** total ash,**[7]** acid insoluble ash,**[8]** viscosity,**[9]** specific gravity,**[10]** acid value,**[11]**saponification value,**[12]** refractive index,**[13]** iodine value,**[14]**Total Solid Content,**[15]** Uniformity of weight,**[16]** Hardness Test**[17]** and Spreadability Test**[18]**

Observations and Results

Organoleptic characters: The organoleptic characters of all raw materials of *Dadrughni Vati* (*Lepa*) (DL) and *Dadrughna Malahara* (DM) are mentioned in table no. 1.

Physicochemical analysis: Physicochemical analysis of *Ashuddha* and *Shuddha Tankana* is shown in table no. 2

Table 1: Showing the organoleptic characters of raw material of DL and DM

SN	Ingredients	Colour	Appearance	Texture	Taste	Odour
1.	Ashuddha Tankana	Translucent / opaque	Crystalline	Rough/ Granular	Bitter, Astringent	Odourless
	Shuddha Tankana	White	Amorphous	Smooth	Bitter, Astringent	Odourless
2.	Ashuddha Sphatika	Translucent	Crystalline	Hard	Astringent	Odourless
	Shuddha Sphatika	Colourless/ Transparent	Amorphous	Smooth	Astringent	Odourless
3.	Ashuddha Gandhaka	Pale Yellow	Crystalline	Hard	Earthy	Characteristic
	Shuddha Gandhaka	Bright Yellow	Amorphous	Smooth	Earthy	Characteristic
4.	Sarjarasa	Brownish white	Powder	Rough	Astringent	Characteristic
5.	Chakramarda	Dark Brown	Hard	Rough	Very bitter	None
6.	Tila Taila	Yellow	Oily	Unctuous	Sweet, Astringent	Characteristic
7.	Siktha	Yellowish white	Greasy	Smooth	Bitter	Characteristic
8.	Jambiri Nimbu	Orange	Oblong, Soft	Smooth	Sour	Citric

Table 2: Physicochemical analysis of *Ashuddha* and *Shuddha Tankana*

SN	Physicochemical analysis	Results		API standard
		Ashuddha	Shuddha	
1.	pH	10.9	10.3	Not mentioned
2.	Loss on drying (% w/w)	27.62	7.61	NMT 30%
3.	Ash value (% w/w)	52.46	54.216	NMT 55%
4.	Acid insoluble Ash (% w/w)	9.60	4.45	NMT 10%
5.	Water soluble extractive (% w/w)	92.97	99.07	Completely soluble
6.	Alcohol soluble extractive (% w/w)	14.53	55.97	Not mentioned

Physicochemical analysis of *Ashuddha* and *Shuddha Sphatika* shown in table no. 3

Table 3: Physicochemical analysis of *Ashuddha* and *Shuddha Sphatika*

SN	Physicochemical analysis	Results		API standard
		Ashuddha	Shuddha	
1.	pH	2.36	2.54	Not mentioned
2.	Loss on drying (% w/w)	35.18	1.94	Not mentioned
3.	Ash value (% w/w)	24.97	53.79	Not mentioned
4.	Acid insoluble Ash (% w/w)	3.62	4.010	Not mentioned
5.	Water soluble extractive (% w/w)	97.70	99.10	Not mentioned
6.	Alcohol soluble extractive (% w/w)	5.70	5.63	Not mentioned

Physicochemical analysis of *Ashuddha* and *Shuddha Gandhaka* is shown in table no. 4.

Table 4: Physicochemical analysis of *Ashuddha* and *Shuddha Gandhaka*

SN	Physicochemical analysis	Results		API standard
		Ashuddha	Shuddha	
1.	pH	9.13	6.04	Not mentioned
2.	Loss on drying (% w/w)	0.5	0.82	Not mentioned
3.	Ash value (% w/w)	4	4.02	Not mentioned
4.	Acid insoluble Ash (% w/w)	1	1.03	Not mentioned
5.	Water soluble extractive (% w/w)	0.079	0.23	Not mentioned
6.	Alcohol soluble extractive (% w/w)	0.15	0.23	Not mentioned

Physicochemical analysis of *Chakramarda Beeja Churna* is shown in table no. 5.

Table 5: Physicochemical analysis of *Chakramarda Beeja Churna*

SN	Physicochemical analysis	Results	API standard
1.	pH	4.70	Not mentioned
2.	Loss on drying (% w/w)	7.81	Not mentioned
3.	Ash value (% w/w)	5.099	NMT 5%
4.	Acid insoluble Ash (% w/w)	0.26	NMT 0.2%
5.	Water soluble extractive (% w/w)	31.13	NLT 14%
6.	Alcohol soluble extractive (% w/w)	16.74	NLT 7%

Physicochemical analysis of *Sarjarasa Churna* shown in table no. 6

Table 6: Physicochemical analysis of *Sarjarasa Churna*

SN	Physicochemical analysis	Results	API standard
1.	pH	4.51	Not mentioned
2.	Loss on drying (% w/w)	2.80	Not mentioned
3.	Ash value (% w/w)	1.41	Not mentioned
4.	Acid insoluble Ash (% w/w)	3.22	Not mentioned
5.	Water soluble extractive (% w/w)	1.90	Not mentioned
6.	Alcohol soluble extractive (% w/w)	28.13	Not mentioned

Table 7: Showing the Physicochemical analysis of *Tila Taila*

SN	Physicochemical analysis	Results	API standard
1.	pH	5	Not mentioned
2.	Specific gravity (g/ml)	0.917	0.9160-0.9190
3.	Viscosity by Ostwald (cp)	22.02	Not mentioned
4.	Refractive index	1.466	1.4650-1.4665
5.	Acid Value	2.77	NMT 2.0
6.	Peroxide Value	5.36	Not mentioned
7.	Saponification Value	204.96	188-195
8.	Iodine Value	103.10	103-116
9.	Rancidity	Not rancid	Not mentioned

Table 8: Showing the Physicochemical analysis of *Jambiri Nimbu Svarasa*

Ingredients	pH	Total solid content
Jambiri Nimbu Svarasa	1.20	5.3

Analysis of the finished product

Organoleptic characters: The organoleptic characters of DL are mentioned in table no. 9.

Table 9: Organoleptic characters of DL

SN	Organoleptic characters	Batch-1	Batch-2	Batch-3
1.	Colour	Brown	Brown	Brown
2.	Appearance	Cylindrical Vati	Cylindrical Vati	Cylindrical Vati
3.	Texture	Hard	Hard	Hard
4.	Odour	Characteristic	Characteristic	Characteristic

The organoleptic characters of DM are mentioned in table no. 10.

Table 10: Organoleptic characters of DM

SN	Organoleptic characters	Batch-1	Batch-2	Batch-3
1.	Colour	Dark Brown	Dark Brown	Dark Brown
2.	Appearance	Uniform cream	Uniform cream	Uniform cream
3.	Texture	Thick oily	Thick oily	Thick oily
4.	Odour	Characteristic	Characteristic	Characteristic

Physicochemical analysis: Physicochemical analysis of DL is shown in table no. 11.

Table 11: Physicochemical analysis of DL

SN	Physicochemical analysis	Observations			
		Batch-1	Batch-2	Batch-3	Average
1.	pH	3.93	3.87	3.97	3.92
2.	Loss on drying (% w/w)	14.20	14.16	13.90	14.08
3.	Ash value (% w/w)	20.04	19.54	19.16	19.58
4.	Acid insoluble Ash (% w/w)	5.76	5.50	5.86	5.70
5.	Water soluble extractive (% w/w)	43.96	44.18	44.22	44.12
6.	Alcohol soluble extractive (% w/w)	13.79	14.19	13.94	13.97
7.	Hardness kg/cm2	10.1	9.7	9.7	9.8
8.	Average weight (mg)	3652	3641	3660	3651

Physicochemical analysis of DM is shown in table no. 12.

Table 12: Physicochemical analysis of DM

SN	Physicochemical analysis	Observations			
		Batch-1	Batch-2	Batch-3	Average
1.	Specific Gravity	0.930	0.930	0.931	0.930
2.	pH	Not detected	Not detected	Not detected	Not detected
3.	Refractive Index	Not detected	Not detected	Not detected	Not detected
4.	Acid Value	2.25	2.17	2.26	2.22
5.	Saponification Value	118.97	117.91	118.83	118.57
6.	Iodine Value	76.95	76.83	77.55	77.11
7.	Viscosity	15,62,000 cp	15,48,000 cp	15,83,000 cp	15,64,333 cp
8.	Spreadability	662.15 g	641.19 g	670.52 g	657.95 g

Discussion

PH indicates the acidity or alkalinity of a solution. A suitable pH range is important for preserving the active compounds and ensuring optimal solubility and absorption.**[19]** The data reveals that pH values of AT, ST, AS, SS, AG, SG, CB andS were 10.9, 10.3, 2.36, 2.54, 9.13, 6.04, 4.70 and 4.51 respectively.

The decreased pH value of *Shodhita Tankana* in comparison to *Ashodhita Tankana* is the hydrous form of borax promotes higher pH levels due to better solvation and ionization of borate ions in the presence of water, whereas the anhydrous form, lacking water, leads to less effective ionization and a lower pH.**[20]**

The degree to which a compound dissociates into its constituent ions when dissolved in water significantly affects the concentration of hydrogen ions (H^+) in thesolution; more complete dissociation leads to the release of more H^+ ions, resulting in a lower pH and a more acidic solution. In the case of potash alum, the anhydrous form may interact with water differently, potentially resulting in a lower degree of H^+ release compared to the hydrous form. This difference in interaction can produce a higher pH in the anhydrous form, indicating a less acidic solution overall.**[21]**

The pH of *Gandhaka* (sulfur) can vary based on its form and purity. In *Ashuddha Gandhaka* may have a more variable pH, due to the presence of impurities or contaminants. *Ashuddha Gandhaka* may contain physical impurities such as foreign particles (e.g., sand and stones) as well as chemical impurities like Inorganic form arsenate or arsenite and other substances.**[22]** These salts can yield a pH that is typically around neutral to slightly alkaline (approximately 7 to 9). ThepH of *Shuddha Gandhaka* istypically neutral to slightly acidic, generally around 6 to 7, depending on the specific purification method and any residual impurities.**[23]**

The pH values of both CB and S are not given in API. However, they comply with the findings from prior research work.**[24,25]**

Loss on drying value of AT, ST, AS, SS, AG, SG, CB andS were 27.62%, 7.61%, 35.18%, 1.94%, 0.5%, 0.82%, 7.81% and 2.80% respectively indicating that the powder has an appropriate moisture content, ensuring stability and preventing microbial growth.**[26]**

Sphatika and *Tankana* both have ahygroscopic nature. The parameter of LOD in AS and SS, AT and ST reveals that After *the Shodhana process, Sphatika* and *Tankana*converted from hydrous to anhydrous form. *Ashuddha Tankana* (sodium tetraborate decahydrate) contains ten water molecules per formula unit. When heated, these water molecules are lost, contributing significantly to the weight loss measured in the loss on drying (LOD) value, resulting in a higher LOD. In contrast, *Shuddha Tankana* (sodium tetraborate pentahydrate) contains less water, so when subjected to the same drying process, it experiences minimal weight loss due to the absence of evaporating water, leading to a low LOD value. **[27]**

The loss on drying (LOD) value for potash alum varies significantly between its hydrous and anhydrous forms due to the presence or absence of water molecules. *Ashuddha Sphatika* (potassium aluminum sulfate dodecahydrate) contains twelve water molecules per formula unit, and when heated or dried, these water molecules are lost, resulting in considerable weight loss and a relatively high LOD value. In contrast, *Suddha Sphatika* (potassium aluminum sulfate) contains no water, so when subjected to drying, there is minimal to no weight loss, leading to a very low or near-zero LOD value. The difference in LOD values between these forms is a key factor in their characterization and applications.**[28]**

The parameter of LOD in AG and SG reveals that the drug has aminor hygroscopic activity with less chance of medication contamination.**[29]** The LOD of both CB and S are not given in API. However, they were compared and as found similar to the findings from previous research work.**[30,31]**

Total ash indicates the inorganic residue remaining after the complete combustion of a herbal sample. It reflects the mineral content and can provide insights into the purity and quality of the sample. **[32]** The data reveals that ash values of AT, ST, AS, SS, AG, SG, CB andS were 54.216%, 52.46%, 24.97%, 53.79%, 4%, 4.02%, 5.099% and1.41% respectively indicative of thepresence of theinorganic compound in samples.Borax (sodium tetraborate) and potash alum (potassium aluminum sulfate) exhibit different ash values between their hydrous and anhydrous forms due to the presence of water in their hydrous structures.

Borax commonly exists as borax decahydrate ($Na_2B_4O_7 \cdot 10H_2O$), where the water molecules are released during combustion, resulting in a lower concentration of borate ions in the ash. In contrast, the anhydrous form contains less water, leading to a higher concentration of borate ions and a higher Ash value.**[33]** Similarly, potash alum is often found as potassium aluminum sulfate dodecahydrate ($KAl(SO_4)_2 \cdot 12H_2O$), and the water in its hydrous form dilutes the metal ion concentration, contributing to a lower Ash value compared to the anhydrous form, which retains a higher concentration of inorganic material after combustion.**[34]**

The total Ash Value in AG and SG does not differ and aligns closely with previous research work.**[35]**

The total Ash value of CB complies with the API standard and theash value of S complies with previous work. Both values are closely similar to those indicating that both drugs are genuine. This parameter indicates the presence of non-soluble minerals, such as silicates or other impurities, that may come from soil or contamination.**[36]**

The human metabolic process and pharmacokinetics depend upon the purity and human-acceptable forms of the drug. When the AT, ST, AS, SS, AG, SG, CB andS were treated with hydrochloric acid, 9.60 %, 4.45 %, 3.62 %, 4.010 %, 1 %, 1.03 %, 0.26 % and 3.22 % respectively, acid-insoluble ash was detected, which signifies the genuineness of the product and suggests it is best in terms of solubility and absorption. As the acid insoluble ash value of AT and ST is within thepermissible limits, samples are not contaminated, showing thegenuineness of thedrug. The acid insoluble ash value in AG and SG does not differ and aligns closely with previous research work.**[37]**

The total acid insoluble ash value of CB meets the API standard, while the acid insoluble ash value of S aligns with prior studies. Both values are quite similar, suggesting that both substances are authentic.

The data reveals that water-soluble extractive values of AT, ST, AS, SS, AG, SG, CB andS were 92.97 %, 99.07 %, 97.70 %, 99.10 %, 0.079 %, 0.23 %, 31.13 % and 1.90 % respectively. This value reflects the presence of water-soluble compounds, such as sugars, amino acids, vitamins, and certain active phytochemicals.**[38]**

The anhydrous form of potash alum (potassium aluminum sulfate, $KAl(SO_4)_2$) exhibits higher solubility in water compared to its hydrated forms primarily due to the absence of water molecules in its structure. This lack of hydration allows for more effective ionic interactions with water, facilitating greater solvation of the ions upon dissolution. As a result, the anhydrous form can dissociate more readily into potassium (K^+), aluminum (Al^{3+}), and sulfate (SO_4^{2-}) ions, leading to enhanced solubility in aqueous environments.**[39]** Similarly, with fewer water molecules associated with its structure, *Shuddha Tankana* can more effectively interact with water, leading to increased solubility.**[40]**

The water-soluble extractive value of CB conforms to the API standard, and water soluble extractive value of S is consistent with earlier research. The close similarity between both values indicates that both drugs are authentic. The data reveals that alcohol soluble extractive values of AT, ST, AS, SS, AG, SG, CB andS were 14.53 %, 55.97 %, 5.70 %, 5.63 %, 0.15 %, 0.23 %, 16.74 % and 28.13 % respectively Alcohol-soluble extractive value reveals the existence of polar components including glycosides, flavonoids, and steroids.**[41]**

The lower alcohol-soluble extractive value of *Sphatika* compared to its water-soluble extractive value is primarily due to the polarity of the solvents. Water, being highly polar, effectively dissolves ionic compounds like those in *Sphatika* through strong hydration and ionic interactions. In contrast, alcohols are less polar and dissolve primarily non-polar or less polar compounds, leading to lower solubility of *Sphatika*. Additionally, the hydrogen bonding capacity of water enhances the solvation of ions, further contributing to the higher water solubility in both *Sphatika***[42]** and *Tankana*.**[43]**

The alcohol soluble extractive value of CB follows API standards, while the alcohol soluble extractive value of S corresponds with findings from previous studies. The similarity between these values suggests that both substances are authentic.

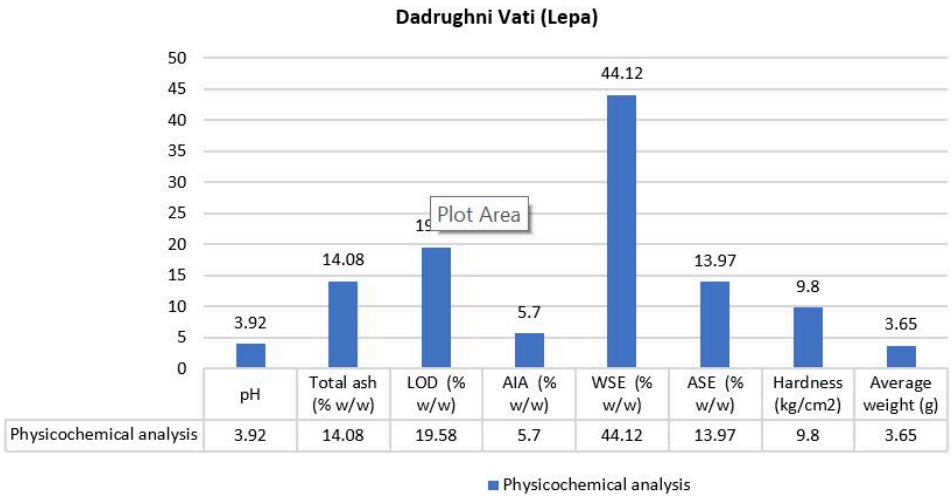
The average pH of DL was 3.92, consistent across all batches. Given that normal skin pH ranges from 4 to 6,**[44]** this pH indicates that the formulation is safe for use with minimal irritation. The average loss on drying (LOD) was 14.08%, similar across batches, attributed to the hygroscopic nature of *Tankana* and *Sphatika*, along with other herbal components, except for *Gandhaka*.

The average ash value of DL was 19.58%, reflecting its inorganic content from both herbs and minerals. This value aligns with the expected ash values of the formulation's ingredients, suggesting no significant adulteration by substances like sand or soil. Additionally, the average acid insoluble ash (AIA) value was 5.70%, indicating high bioavailability; AIA can hinder skin absorption and reduce the efficacy of active ingredients.**[45]**

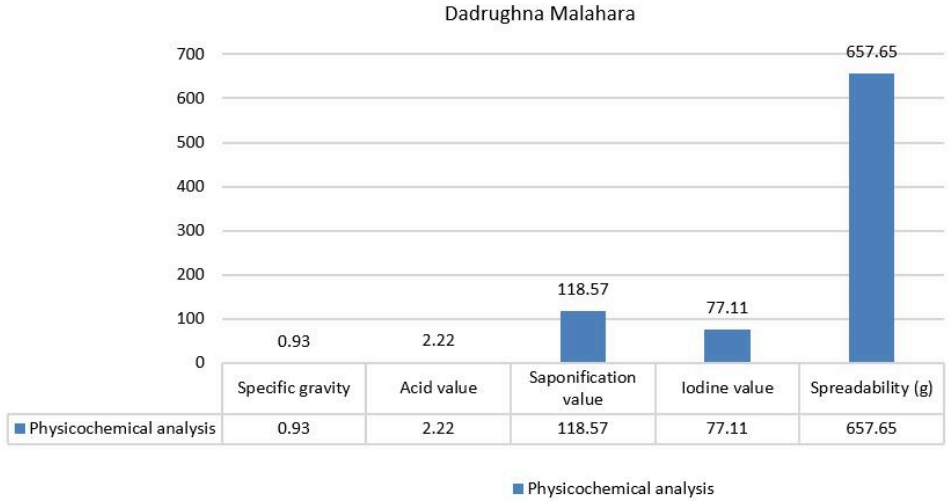
The average water-soluble extractive value was 44.12%, compared to 13.97% for alcohol-soluble extractives. The higher water-soluble extractives enhance the bioavailability of hydrophilic active ingredients, making the formulation milder and suitable for a broader range of users. These components also improve moisturizing properties, **[46]** aiding skin hydration, and making DL beneficial for conditions like *Dadru* with symptoms of *Kandu* and *Rukshta*. The average hardness of DL was 9.8, and the average weight was 3651 mg (3.65 g), both uniform across all batches. Tablet hardness is essential for mechanical strength, manufacturing quality, patient compliance, and overall stability. All *Vati* was consistent in weight. The average specific gravity of DM was 0.930, consistent across all batches, influencing the spreadability and absorption of the formulation lower specific gravity allows for easier spreading and faster absorption. **[47]** The average acid value was 2.22, indicating a minimal level of free fatty acids, suggesting the formulation is milder and suitable for sensitive skin. This low acid value also correlates with better stability, as higher values can indicate degradation while maintaining effective emollient properties for improved skin feel and moisture retention.**[48]**

The average saponification value of DM was 118.57, indicating a significant presence of short- and medium-chain fatty acids. This suggests good emulsifying properties, enhancing ointment stability, and contributing to smoother texture and better spreadability, facilitating improved absorption of active ingredients.**[49]**

The average iodine value was 77.11, indicating some unsaturation and making the formulation less prone to oxidation and rancidity, thus enhancing stability and shelf life.**[50]** Iodine, acid, and saponification values serve as indicators of rancidity related to free fatty acid liberation. The average viscosity of DM was 15,64,333 cp, and the average spreadability was 657.95, both consistent across all batches.



Graph 1: Comparative physicochemical analysis of DL



Graph 2: Comparative physicochemical analysis of DM

Conclusion

The analytical profile of *Dadrughni Vati* (*Lepa*) (DL) showed average values for pH (3.92), LOD (14.08%), Ash value (19.58%), Acid-insoluble Ash (5.70%), water-soluble extractives (44.12%), alcohol-soluble extractives (13.97%), hardness (9.8), and weight (3651 mg), while *Dadrughna Malahara* (DM) exhibited average values for specific gravity (0.930), acid value (2.22), saponification value (118.57), iodine value (77.11), viscosity (15,64,333 cp), spreadability (657.95 g).

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