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PHARMACEUTICO-ANALYTICAL AND AYURVEDIC PHARMACOLOGICAL PROFILE OF NISHAMALAKI CAPSULE AND ITS CONSTITUENTS IN PURVIEW OF PRAMEHA WITH RESPECT TO TYPE 2 DIABETES MELLITUS

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ABSTARCT

This study conducts a detailed pharmaceutical and pharmacological evaluation of Nishamalaki Capsule, a phytomedicinal preparation composed of *Curcuma longa* (turmeric) and *Emblica officinalis* (amla). The research emphasizes formulation standardization through comprehensive physicochemical and microbial analyses, performed in adherence to both Ayurvedic Pharmacopoeia of India (API) and contemporary quality control norms. Analytical results confirmed optimal parameters: moisture content (6.245%), total ash (5.034%), acid-insoluble ash (0.641%), water-soluble extractive (30.434%), and alcohol-soluble extractive (22.346%), alongside a rapid disintegration time of 10 minutes and the absence of specified microbial

contaminants. Pharmacological assessment underscores the formulation's multi-target potential in Type 2 Diabetes Mellitus, driven by synergistic bioactive compounds including curcuminoids and emblicanin derivatives. These constituents are documented to enhance insulin sensitivity, mitigate oxidative stress, modulate inflammatory pathways, and improve lipid profiles. The study confirms the formulation's compliance with quality benchmarks, reinforcing its reliability and therapeutic promise in the integrative management of diabetes and associated metabolic dysfunctions. Further robust clinical trials are recommended to validate its efficacy and long-term safety.

Keywords: Nishamalaki Capsule, Diabetes Mellitus, Standardization, Phytoconstituents, Metabolic Regulation

INTRODUCTION:

Diabetes mellitus is a major global public health concern with significant morbidity, mortality, and economic burden. Despite advances in medical care, diabetes remains one of the most prevalent noncommunicable diseases worldwide **[1]**. The global prevalence of diabetes is increasing at an alarming rate. According to the International Diabetes Federation (IDF), the number of people living with diabetes is projected to reach 693 million by 2024, rising from 451 million in 2017 among individuals aged 18 to 99 years **[2]**. Alarmingly, nearly half of individuals with diabetes remain undiagnosed **[3–4]**. In India with an estimated population of 8.7 percent in the age group of 20–70 years **[5]**. In this context, Ayurvedic medicines have gained importance as a complementary approach in the management of diabetes, particularly in India, where they are commonly used for the treatment of various diseases, including diabetes mellitus. Ayurvedic interventions focus on individualized treatment involving herbal formulations like nishaamalaki churna, katakkhadiradhi kashayam, dietary guidelines, and lifestyle modifications that support glycemic control. However, despite their widespread use, the safety and effectiveness of these drugs need to be further established through well-designed clinical studies. Some drugs which are effective in diabetes are nishaamalaki churna, nishakathakadhi kashayam, kathakadhiradhi kashayam etc. in which we mainly focus on nishamalaki it is time-tested ayurvedic drug describe in text in the managmet of prameha and allied metabolic disorders. Nishaamalaki is combination of Haridra (*Curcuma longa* L) and Amalaki (*Emblica officinalis* . Gareth). The formulation exhibits antihyperglycemic activity along with insulin-sensitizing effects. Curcuma longa and its active constituent

curcumin have been shown to reduce hyperglycemia-induced inflammation and enhance pancreatic β-cell function, leading to improved insulin secretion and overall improvement in the prediabetic state **[6]**. *E. officinalis* fruit has demonstrated its efficacy in lowering hyperglycemia and decreasing oxidative stress in both preclinical and clinical studies **[7]**.

METHODS

Data for the review of literature was collected through classical texts of ashtanga hridhya, ayurveda pharmacopoeia of india (API) and ayurveda formulary of india (AFI). The Drugs & Cosmetics Act, 1940, Rule 160-D. In-house specifications for proprietary formulations. The contemporary review was done from textbooks of bio-medical medicine and peer review research journals on scopus, Elsevier, pubmed and other relevant databases. In addition, the pharmacological activities, chemical composition, ayurveda quality of each ingredient in nishamalaki churna were assessed.

Classical reference of Nishamalaki churna: It is widely used and research backed ayurveda formulation in the spectrum of prameha with respect to type 2 Diabetes mellites, the reference dealt with in this paper is from the AFI, derived from Astanga Hridhya Chikitshasthana 12/5 **[8]**. Several studies show the efficacy of nishamalaki churna in diabetes based on previous clinical studies also the clinical efficacy and safety of same have been tested in multicentric studies, the classical reference of nishamalaki churna is based on Astanga Hridhya.

Table 1: nishamalaki churna is based on Astanga Hridhya.

Drug	Botanical name	Part used	Quantity
Nisha (Haridra)	*Curcuma longa*	Rhizome powder	250mg
Amalaki	*Embilica officinalis*	Phala (Dried fruit)	250mg
-	Excipients (as required)	q.s.	-
Capsule shell	Vegetarian (HPMC) or gelatin	1 capsule	-

Method of Preparation of nishamalaki churna as per Classical and Modern Standards: Purification & Powdering: Amalaki fruits are cleaned, dried, and finely powdered. Haridra rhizomes are washed, dried and powdered separately. Sieving & Mixing: Both powders are sieved through an 80-mesh sieve to ensure uniform particle size. Powders are mixed geometrically to achieve homogeneity. After preparation the churnas we filled the churnas into capsules for which it is easy to take, easy to store. Encapsulation: The blended powder is filled into empty capsule shells using an automatic capsule-filling machine. Capsule weight is standardized to 500 mg per capsule (or as per

formulation design). Quality Control: Capsules are tested for weight variation, disintegration time, microbial limits, and physicochemical parameters as per API guidelines. Pharmaceutical Form: Hard gelatin or vegetarian capsule

Pharmaceutical Analysis of nishamalaki churna capsule: Parameters Assessed: In Microbial Tests: Qualitative and quantitative analysis for *E. coli, S. aureus, P. aeruginosa, S. abony*, total bacterial count, and total fungal count. In Physicochemical Tests: Moisture content, total ash, acid-insoluble ash, water-soluble extractive, alcohol-soluble extractive, pH, disintegration time, and organoleptic evaluation.

Instrumentation: Standard laboratory equipment was used, including hot air ovens, muffle furnace, disintegration test apparatus, and microbial incubators.

RESULTS

Organoleptic and Physicochemical Analysis of Amalaki Churna

The test sample of Amalaki Churna, Batch No. II, was submitted by KLE Ayurved Pharmacy for quality analysis at the Central Research Facility of Shri B M Kankanawadi Ayurveda Mahavidyalaya. The sample, manufactured in January 2025 with an expiry date of December 2026, was analyzed for organoleptic and physicochemical parameters as per API standards on 11/01/2025 (Reference No: CRF/FG/07/2025-26). The macroscopic evaluation confirmed the sample as a churna with dark brown colour, astringent taste, and characteristic odour, while physicochemical tests revealed moisture content of 6.129%, ash value of 2.977%, acid-insoluble ash of 0.982%, water-soluble extractive of 53.243%, and alcohol-soluble extractive of 43.829%, all complying with API specifications and confirming the sample's standard quality. Which is mention in **Table 2** & microbial analysis is also mention in **Table 3**.

Table 2: Organoleptic and Physicochemical Analysis of Amalaki Churna

Parameter	Limit (API)	Result
Form	Churna	Churna
Colour	Dark brown	Dark brown
Taste	Astringent	Astringent
Odour	Characteristic	Characteristic
Moisture Content (%)	NMT 12%	6.129%
Total Ash (%)	NMT 7%	2.977%
Acid Insoluble Ash (%)	NMT 2%	0.982%
Water Soluble Extractive (%)	NLT 50%	53.243%
Alcohol Soluble Extractive (%)	NLT 40%	43.829%

(NMT – Not more than, NLT - Not less than)

Table 3: Microbial Analysis of Amalaki Churna

Test Organism	Limit	Result
E. coli	Absent/100ml	Absent

S. aureus	**Absent/100ml**	**Absent**
P. aeruginosa	**Absent/100ml**	**Absent**
S. abony	**Absent/100ml**	**Absent**
Total Bacterial Count	**30–300 cfu/ml**	**No growth**
Total Fungal Count	**10–100 cfu/ml**	**No growth**

Organoleptic and Physicochemical Analysis of Haridra Churna

The test sample of Haridra Churna, Batch No. 1, was submitted by KLE Ayurved Pharmacy for quality evaluation at the Central Research Facility of Shri B M Kankanawadi Ayurveda Mahavidyalaya. The sample, manufactured in June 2024 with an expiry date of May 2026, underwent organoleptic and physicochemical analysis as per API standards on 19/06/2024 (Reference No: CRF/FG/197/2024-25). Macroscopic examination identified the sample as a churna with bright yellow colour, characteristic taste, and aromatic odour. Physicochemical assessment reported loss on drying of 8.959%, ash value of 7.121%, acid-insoluble ash of 0.846%, water-soluble extractive of 13.411%, and alcohol-soluble extractive of 9.413%, all within API limits, confirming the sample's standard quality. Which mention in **Table 4** & microbial analysis is also mention in **Table 5**.

Table 4: Organoleptic and Physicochemical Analysis of Haridra Churna

Parameter	Limit (API)	Result
Form	**Churna**	**Churna**
Colour	**Bright yellow**	**Bright yellow**
Taste	**Characteristic**	**Characteristic**
Odour	**Aromatic**	**Aromatic**
Moisture Content (%)	**NMT 12%**	**8.959%**
Total Ash (%)	**NMT 9%**	**7.121%**
Acid Insoluble Ash (%)	**NMT 1%**	**0.846%**
Water Soluble Extractive (%)	**NLT 12%**	**13.411%**
Alcohol Soluble Extractive (%)	**NLT 8%**	**9.413%**

(NMT – Not more than, NLT - Not less than)

Table 5: Microbial Analysis of haridra Churna

Test Organism	Limit	Result
E. coli	**Absent/100ml**	**Absent**
S. aureus	**Absent/100ml**	**Absent**
P. aeruginosa	**Absent/100ml**	**Absent**
S. abony	**Absent/100ml**	**Absent**
Total Bacterial Count	**30–300 cfu/ml**	**No growth**
Total Fungal Count	**10–100 cfu/ml**	**No growth**

Analysis of Nishamalaki Capsule

The test sample of Nishamalaki Capsule, Batch No. 1, was submitted by KLE Ayurved Pharmacy for microbial quality assessment at the Central Research Facility of Shri B M Kankanawadi Ayurveda Mahavidyalaya. The sample, with an expiry date of December 2026, underwent microbiological testing as

per API and in-house specifications on 16/01/2025 (Reference No: CRF/FG/06/2025-26). Qualitative microbial analysis confirmed the absence of *E. coli, S. aureus, P. aeruginosa,* and *S. abony*. Quantitative microbial limits showed no growth in total bacterial count and total fungal count. The sample complied with all specified microbial standards and was certified as standard quality. Detailed mentioned in **Table 6** & Microbial Analysis of Nishamalaki Churna Capsule is in **Table 7**.

Table 6: Analysis of Nishamalaki Capsule

Parameter	Result
Form	Capsule
Colour	Yellowish
Taste	Astringent
Odour	Aromatic
Moisture Content (%)	6.245%
Total Ash (%)	5.034%
Acid Insoluble Ash (%)	0.641%
Water Soluble Extractive (%)	30.434%
Alcohol Soluble Extractive (%)	22.346%
Disintegration Time	10 minutes

Table 7: Microbial Analysis of Nishamalaki Churna Capsule

Test Organism	Limit	Result
E. coli	Absent/100ml	Absent
S. aureus	Absent/100ml	Absent
P. aeruginosa	Absent/100ml	Absent
S. abony	Absent/100ml	Absent
Total Bacterial Count	30–300 cfu/ml	No growth
Total Fungal Count	10–100 cfu/ml	No growth

Table 8: Ayurveda Pharmacological action of drugs in nishamalaki churna capsule:

Drug Name	Latin Name	Rasa	Virya	Vipaka	Guna	Doshaghanta
Amalki	*Emblica officianalis*	Panchras, lavanvarjit	Sheeta	Madhur	Guru,Ruksha, Sheeta	Tridoshahar
Haridra	*Curcuma longa*	Tikta, katu	Ushna	Katu	Laghu, Teeshan	Kapha-Pitta shamana

DISCUSSION:

In texts description of nishamalaki churna is give but Nishamalaki Capsule is a proprietary Ayurvedic formulation. Here we are preparing capsules because capsules are easy to take and easy to store as compare to churnas. It is important to note that no official API standards are currently available for Nishamalaki Capsule as it is a proprietary formulation, but for Nisha and amalaki churna which is filled in capsule are available so in this we follow that standard of churnas. Nishamalki churna is preparation made with ingredients namely amalaka, haridra as per the pharmacopeial standards. for Amalaki Churna, The Ayurvedic Pharmacopoeia of India (API) monograph defines standards for identity, purity, and strength, including total ash (≤7%), acid-insoluble ash (≤2%), alcohol-soluble extractive (≥40%), water-soluble

extractive (≥50%), and foreign matter (≤2%). The laboratory analysis of the tested batch—with total ash at 2.977%, acid-insoluble ash at 0.982%, alcohol-soluble extractive at 43.829%, and water-soluble extractive at 53.243% - confirms full compliance with API specifications, reflecting high purity and adequate extraction of bioactive components. Although foreign matter was not assessed, the low ash values suggest minimal inorganic adulteration. The moisture content of 6.129% falls within the typical API limit for churna (≤12%). For Haridra Churna the API monograph stipulates identity and quality parameters including foreign matter (≤2%), total ash (≤9%), acid-insoluble ash (≤1%), alcohol-soluble extractive (≥8%), water-soluble extractive (≥12%), and volatile oil content (≥4%). The test report for Batch No. 1 indicates full compliance with the physicochemical standards assessed: total ash at 7.121% (within ≤9%), acid-insoluble ash at 0.846% (within ≤1%), alcohol-soluble extractive at 9.413% (exceeds ≥8%), and water-soluble extractive at 13.411% (exceeds ≥12%). The loss on drying (moisture) was 8.959%, which is within the general API limit of ≤12% for churna. Organoleptic properties-bright yellow color, aromatic odor, and characteristic taste-also align with the expected profile of pure turmeric powder. Notably, foreign matter and volatile oil content were not tested in this report; however, the sample's low acid-insoluble ash suggests minimal inorganic impurities. Overall, these two batches meet the specified API standards for purity, strength, and identity, confirming it as a standard quality formulation suitable for therapeutic use. Now the capsule is filled with both churnas. The Nishamalaki churna capsule sample tested showed a yellowish colour, astringent taste, and aromatic odour, presented in a capsule form. Each capsule exhibited a moisture content of 6.245%, total ash of 5.034%, and acid-insoluble ash of 0.641%. The water-soluble extractive value was 30.434%, while the alcohol-soluble extractive value was 22.346%. The disintegration time was recorded as 10 minutes, which is acceptable for capsule formulations and ensures proper release of active ingredients in the gastrointestinal tract.

Nishamalaki capsule composed of haridra and amalaki. Haridra helps alleviate cellular obstructions and restores normal cellular function. Pharmacological research indicates that Haridra (Turmeric rhizome powder) is highly effective when administered with Amla juice and honey in managing Diabetes mellitus **[9]**. Ingesting 6 g of Curcuma longa has been shown to elevate postprandial serum

insulin levels in healthy individuals, although it does not appear to influence plasma glucose levels or glycemic index, suggesting a potential role in modulating insulin secretion **[10]**. The active compounds in turmeric rhizome, known as curcuminoids, reduce lipid peroxidation by sustaining elevated activity of antioxidant enzymes such as superoxide dismutase, catalase, and glutathione peroxidase. The antioxidant capacity of Curcuma longa is attributed to curcumin and its derivatives—demethoxycurcumin, bisdemethoxycurcumin, and diacetylcurcumin **[11]**. Systematic scientific investigation supports the antidiabetic, hypolipidemic, and hepatoprotective properties of freeze-dried turmeric rhizome powder dissolved in milk, indicating its potential as a safe and effective dietary supplement for diabetes management **[12]**. *Curcuma longa* contains various bioactive constituents including curcuminoids, glycosides, terpenoids, and flavonoids. Extracts of turmeric in isopropanol and acetone have demonstrated significant inhibitory effects on Human Pancreatic Amylase (HPA), thereby reducing starch hydrolysis and subsequently lowering blood glucose levels **[13]**.

The anti-diabetic property of Amalaki has been attributed to its constituents viz. ellagic acid which stimulates the pancreatic β-cells to secrete insulin **[14]** and gallic acid, which has been shown to up-regulate pAkt, PPAR-γ and Glut4 pathways thus improving insulin sensitivity **[15]**. The antioxidant properties of *E. officinalis* extracts and their impact on oxidative stress were investigated in streptozotocin-induced diabetic rats. Amalaki exhibited potent inhibition of advanced glycosylated end product formation - a marker of oxidative stress linked to protein glycosylation. Additionally, Amalaki significantly lowered thiobarbituric acid-reactive substance levels, indicating a reduction in lipid peroxidation. The treatment also modulated levels of albumin and adiponectin, which were decreased in diabetic rats **[16]**. Hypolipidemic action of Amalaki demonstrates potential efficacy in managing hypercholesterolemia and in the prevention of atherosclerosis. Both fresh juice and ethyl acetate extract of Amalaki have shown a serum lipid-lowering effect. Administration of Amalaki significantly reduced serum cholesterol, triglycerides, phospholipids, and LDL levels **[17-20]**. Immunomodulatory action of *Emblica officinalis*, it contributes notably to immune system stimulation. It enhances natural killer cell activity and antibody-dependent cellular cytotoxicity. Given its recognition as a rich source of

vitamin C, the immunomodulatory properties of *Emblica officinalis* are attributed to its ascorbic acid content, which is well-documented for its immune-stimulating effects **[21]**.

CONCLUSION

Nishamalaki Capsule represents a scientifically validated Ayurvedic formulation with significant therapeutic potential, particularly in conditions involving oxidative stress, inflammation, and metabolic imbalance. The comprehensive pharmaceutical analysis confirms its standardization, safety, and quality, ensuring batch-to-batch consistency and clinical reliability. The formulation's bioactive profile, rapid disintegration, and absence of microbial contamination align with modern pharmaceutical expectations while remaining rooted in Ayurvedic principles. This study supports the role of Nishamalaki Capsule as a safe and effective Ayurvedic intervention, worthy of further clinical investigation to fully elucidate its therapeutic mechanisms and long-term benefits in targeted health conditions.

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