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Pharmaceutico-Analytical Standardization of Darvyadi Eye Drops with Special Emphasis on HPTLC Profiling

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Abstract

Darvyadi Yoga is a classical formulation indicated in Kaphaja Abhishyanda described in Sushruta Samhita under Netra Rogas. The present study was aimed to carry out pharmaceutico-analytical standardization of Darvyadi Eye Drops prepared as Arka (distillate) with special emphasis on High-Performance Thin-Layer Chromatography (HPTLC) profiling.

Darvyadi Eye Drops were prepared according to classical references of Sharangadhara Samhita (Arka Kalpana). Organoleptic evaluation, physicochemical analysis, and HPTLC fingerprinting were performed as per Ayurvedic Pharmacopoeia of India and WHO guidelines. Silica gel 60 F254 was used as stationary phase and Toluene: Ethyl acetate: Methanol: Formic acid (2:2:1:0.5 v/v/v/v) as mobile phase.

The formulation was colourless, clear, and free from particulate matter. Physicochemical parameters showed near-neutral pH suitable for ophthalmic use. HPTLC profiling revealed distinct, well-resolved bands at 254 nm and 366 nm confirming presence of multiple phytoconstituents. The reproducible Rf values indicate batch-to-batch consistency.

Darvyadi Eye drops demonstrated acceptable organoleptic, physicochemical, microbiological, and chromatographic parameters. The HPTLC fingerprint can serve as a standard reference profile for quality control and future clinical research.

Key words : Darvyadi Eye Drops, Kaphaja Abhishyanda, HPTLC, Arka Kalpana, Ayurvedic ophthalmic formulation.

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Kaphaja Abhishyanda is described under Sarvagata Netra Rogas in Ayurvedic classics and is characterized by excessive discharge, itching, heaviness of eyelids, redness, and stickiness due to Kapha dosha vitiation[14]. Clinically, it closely resembles acute mucopurulent conjunctivitis, a commonly encountered ocular condition in outpatient practice[6]. Conventional management relies on topical antibiotics and anti-inflammatory agents; however, irrational and prolonged use has contributed to antimicrobial resistance and ocular surface toxicity[21]. Ayurveda advocates Kriyakalpa procedures and herbal formulations possessing Kapha-shamaka, Shothahara, Krimighna, and Chakshushya properties[17]. Darvyadi Yoga, described for Kaphaja Netra Rogas, has been adapted into a distilled ophthalmic preparation (Arka) to enhance sterility, stability, and patient acceptability[16]. Standardization through modern analytical techniques such as HPTLC is essential to ensure quality, reproducibility, and clinical reliability[8].

Ocular ailments, particularly those characterized by inflammation or infection, often necessitate interventions beyond conventional pharmaceutical approaches, especially given concerns regarding antimicrobial resistance and ocular surface toxicity arising from prolonged topical antibiotic and anti-inflammatory agent use.

This context underscores the escalating relevance of exploring traditional therapeutic modalities, such as Ayurvedic formulations, which often comprise multifaceted phytochemical profiles conferring broad-spectrum pharmacological activities with potentially reduced adverse effects. Among these, Darvyadi Eye Drops, a classical Ayurvedic ophthalmic formulation, is particularly noted for its traditional application in conditions like Kaphaja Abhishyanda, suggesting its potential in managing inflammatory and infectious ocular states.

However, the inherent complexity of multi-component herbal preparations, such as Darvyadi Eye Drops, presents significant challenges in standardization compared to conventional allopathic medicines due to the vast number of phytoconstituents present This complexity necessitates robust analytical methods to ensure consistency, quality, and efficacy across different batches, a critical aspect for global acceptance and regulatory compliance of Ayurvedic medicines.

Consequently, developing comprehensive standardization protocols, including physico-chemical analysis and advanced chromatographic techniques like High-Performance Thin-Layer Chromatography profiling, becomes imperative for validating the therapeutic claims and ensuring the consistent quality of such polyherbal formulations.

Darvyadi Eye Drops were prepared as a medicated distillate (Arka) following classical Sharangadhara Samhita principles. All raw drugs of Darvyadi Yoga were procured from a certified local supplier and authenticated by the Department of Pharmacognosy. Drugs were then coarsely powdered. Water was added in double quantity of the drug weight and kept for overnight soaking (approximately 10–12 hours). After soaking, an equal quantity of water was added again to the mixture. Mild to moderate heat was applied.

The entire mixture was transferred to a distillation apparatus. Vapours passed through a condenser, where they were cooled and converted back into liquid form. The condensed liquid (distillate) was collected in a sterile receiver. The collected distillate (Arka) was filtered through sterile filter paper. The final Darvyadi Eye Drops were filled into sterile, airtight ophthalmic containers. The analytical evaluation was conducted at the Central Research Laboratory, Parul Institute of Ayurved, Vadodara, in accordance with the Ayurvedic Pharmacopoeia of India and WHO guidelines[3,19]. The finished formulation was subjected to organoleptic evaluation, physicochemical analysis, and HPTLC fingerprinting.

Organoleptic parameters :

Table-1. Organoleptic evaluation of Darvyadi Eye Drops

Parameter	Observation
Colour	Colourless
Clarity	Clear, transparent
Odour	Mild, pleasant
Consistency	Liquid

Physicochemical parameters :

Table-2. Physicochemical parameters of Darvyadi Eye Drops

Sr.no.	Parameter	Value
1.	P^H Value	6
2.	Specific Gravity	1.0004
3.	Viscosity	0.6293
4.	Total Solid content (% w/w)	0.06
5.	Total Ash Value (%w/w)	0

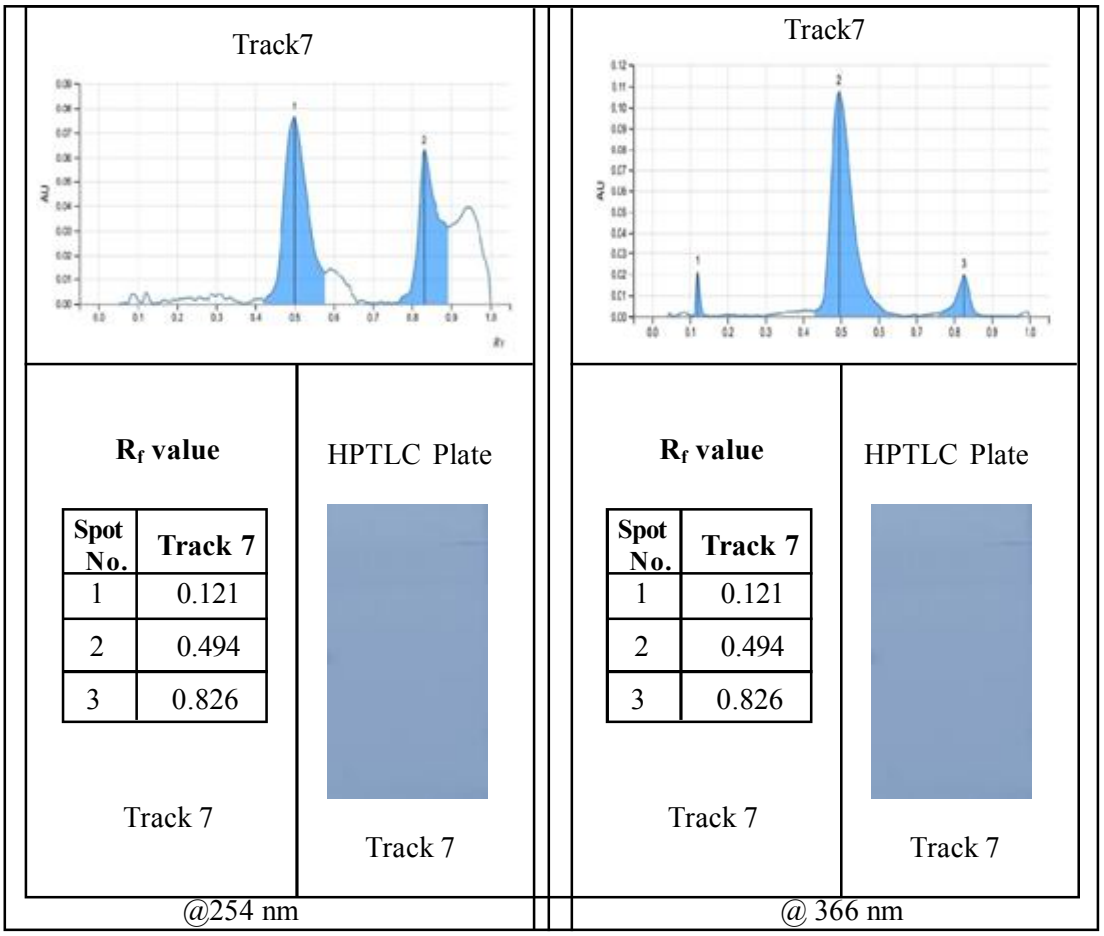
HPTLC fingerprinting was performed to establish the phytochemical identity and batch-to-batch consistency of Darvyadi Eye Drops. Chromatographic separation on silica gel 60 F_{254} using Toluene : Ethyl acetate : Methanol : Formic acid (2:2:1:0.5 v/v/v/v) yielded well-resolved bands, indicating optimal polarity balance of the solvent system[2,13].

Table-3. HPTLC analytical conditions for Darvyadi Eye Drops

HPTLC Fingerprinting Report	
Sample : **Darvyadi Eye Drops**	
Preparation of Test solution: Medicated distillated liquid (Darvyadi eye drops) is used as a Test solution thus obtained for HPTLC fingerprinting.	
Chromatographic Conditions :	
Application Mode	CAMAG Linomat 5 (S/N: 280008) Applicator
Filtering System	Simple filter
Stationary Phase	MERCK - HPTLC Silica gel 60 F_{254} on Aluminium sheets
Application (Y axis) Start Position	15 mm
Development End Position	80 mm from the plate base
Sample Application Volume	15.0 µL
Distance Between Tracks	21.4 mm
Development Mode	CAMAG TLC Twin Trough Chamber
Chamber Saturation Time	30 minutes
Mobile Phase (MP)	Toluene:Ethyl acetate:Methnol:Formic acid (2:2:1:0.5) v/v/v/v)
Visualization	@ 254 nm, @366 nm
Derivatization mode	CAMAG – Dip tank for about 1 minute
Drying Mode, Temp. & Time	TLC Plate Heater Preheated at 100± 5^0C for 3 minutes

Organoleptic evaluation is a critical preliminary quality assessment for ophthalmic preparations, as it directly influences ocular safety and patient compliance. Darvyadi Eye Drops were colourless and transparent, indicating effective filtration and absence of particulate matter, thereby minimizing the risk of mechanical irritation to ocular tissuesy. The formulation possessed a mild, pleasant odour without any off-smell, suggesting absence of degradation or microbial contamination[7]. Uniform liquid consistency facilitates accurate dosing and smooth instillation, which is particularly important in pediatric and geriatric populations[18].

Physicochemical analysis revealed a near-neutral pH, appropriate viscosity, and minimal solid content. Near-neutral pH is desirable for ophthalmic preparations to prevent irritation and reflex lacrimation[11]. Appropriate viscosity ensures adequate ocular surface contact time without compromising comfort, while minimal solid content indicates formulation purity and stability[12].



At 254 nm, UV-absorbing phytoconstituents such as alkaloids and phenolic compounds were observed, while visualization at 366 nm revealed fluorescent bands suggestive of flavonoids and related phenolic derivatives known for antioxidant and anti-inflammatory activity[4,9,10]. Consistency of Rf values across observations confirms formulation stability and batch-to-batch reproducibility[20]. From an Ayurvedic pharmacodynamic perspective, the presence of multiple phytoconstituents supports the concept of Samyoga, wherein synergistic interaction of drugs enhances therapeutic efficacy. This chemically diverse profile correlates with the classically described Shothahara, Krimighna, Kledahara, and Chakshushya actions of Darvyadi formulations in the management of Kaphaja Abhishyanda[5,15].

The present pharmaceutico-analytical study confirms that Darvyadi Eye Drops possess acceptable organoleptic characteristics, physicochemical stability, and a reproducible HPTLC fingerprint profile. The generated chromatographic pattern serves as a reliable quality control marker, providing scientific

validation for its classical use in Kaphaja Abhishyanda and supporting further clinical evaluation and wider ophthalmic application.

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