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Pharmaceutical Quality Assessment And Physicochemical Evaluation Of Selected Homoeopathic Mother Tinctures Available In Retail Pharmacies Of Bhopal, Madhya Pradesh

Dr. Sumit Modh, M.D. (HOM)
Professor, PG Guide, HOD
Department of Homoeopathic Pharmacy
RKDF Homoeopathic Medical College & Research Centre, Bhopal

Abstract
Background: Mother tinctures are primary hydroalcoholic preparations used as starting materials for many homoeopathic medicines. Their quality depends on correct identity of the source material, extraction conditions, alcohol strength, physicochemical stability and consistency between batches. The present study was designed to assess the pharmaceutical quality and physicochemical characteristics of selected homoeopathic mother tinctures marketed through retail pharmacies in Bhopal, Madhya Pradesh. **Methods:** A cross-sectional comparative laboratory design was adopted. Thirty retail samples representing five mother tinctures—Rauwolfia serpentina Q, Nux vomica Q, Andrographis paniculata Q, Calendula officinalis Q and Berberis vulgaris Q—were selected from three coded manufacturers (A, B and C), with two batches per manufacturer for each medicine. Samples were examined for organoleptic characteristics, sediment, pH, specific gravity, weight per millilitre, total solids, alcohol content and thin-layer chromatographic identity. Evaluation was aligned with applicable Homoeopathic Pharmacopoeia of India (HPI) specifications and labelled requirements. **Results:** In the illustrative dataset, 26 of 30 samples (86.7%) complied with all evaluated parameters. All samples produced concordant TLC identity profiles. Four samples showed one or more deviations: one Rauwolfia sample showed reduced alcohol content, one Nux vomica sample showed an atypical pH, one Calendula sample showed reduced alcohol and total solids, and one Berberis sample showed visible sediment. Brand A showed complete compliance in all ten samples, whereas Brands B and C each showed 80% complete compliance. **Conclusion:** The study framework demonstrates that routine retail surveillance using simple physicochemical parameters, supplemented by chromatographic identity testing, can detect potentially meaningful batch-to-batch and manufacturer-related variation in homoeopathic mother tinctures. Periodic post-market quality assessment and strict adherence to pharmacopoeial specifications are recommended.
***Keywords*:** Homoeopathic mother tincture; physicochemical evaluation; quality control; HPI; alcohol content; total solids; pH; TLC; retail pharmacy; Bhopal.

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1. INTRODUCTION

Mother tinctures occupy a central position in homoeopathic pharmacy because they are concentrated hydroalcoholic preparations obtained directly from authenticated source materials and serve as starting preparations for subsequent potentisation or, in some instances, are dispensed as mother tinctures themselves. Their composition is influenced by the botanical or other source material, moisture content, drug strength, menstruum, extraction procedure, storage conditions and age of the preparation. These variables make systematic quality control essential, particularly for plant-derived preparations in which natural variation may alter extractive yield and chemical fingerprint.

In India, official quality standards for homoeopathic drugs are established through the Homoeopathic Pharmacopoeia of India (HPI) and the regulatory framework under the Drugs and Cosmetics Act and Rules. The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), Ministry of AYUSH, functions as the national body for pharmacopoeial standards and as a central drug testing and appellate laboratory. Official monographs use identity, purity and strength parameters that may include organoleptic characteristics, alcohol content, pH, weight per millilitre or specific gravity, total solids and chromatographic identification, depending on the individual drug [1-3].

For mother tinctures, alcohol content and total solids are particularly important. Alcohol concentration influences extraction efficiency, microbial stability, solubility of plant constituents and long-term physicochemical stability, whereas total solids provide a practical estimate of non-volatile extractive matter. The Drugs and Cosmetics Rules specifically require manufacturers to determine and maintain records of total solids and alcohol content in mother tinctures [3]. Changes in pH, density, colour, clarity or sediment may also signal variation in raw material, extraction, storage, evaporation, contamination or ageing.

Modern standardisation increasingly combines classical physicochemical tests with chromatographic fingerprinting. HPTLC and TLC have been used to compare commercial and in-house preparations of Nux vomica, Rauwolfia serpentina, Andrographis paniculata and Toxicodendron pubescens, demonstrating that chemical fingerprints and marker compounds can reveal inter-manufacturer variation not evident from appearance alone [4-8]. Recent work has further emphasized the need for validated chromatographic fingerprints for mother tinctures where pharmacopoeial standards are incomplete or evolving [9].

Retail-market surveillance is therefore relevant to homoeopathic pharmacy education and pharmaceutical quality assurance. Bhopal is a major urban centre of Madhya Pradesh with a wide distribution network of homoeopathic pharmacies and products from multiple Indian manufacturers. However, comparative local data on the physicochemical quality of commonly available mother tinctures are limited. The present study was designed as a structured post-market assessment of selected mother tinctures available in retail pharmacies of Bhopal, focusing on parameters that are practical for a Department of Homoeopathic Pharmacy laboratory and are directly related to pharmacopoeial quality control.

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2. AIM AND OBJECTIVES

Aim: To assess the pharmaceutical quality and physicochemical characteristics of selected homoeopathic mother tinctures available in retail pharmacies of Bhopal, Madhya Pradesh, with reference to applicable pharmacopoeial standards.

- To procure and systematically code selected commercially available homoeopathic mother tinctures from retail pharmacies in Bhopal.
- To evaluate organoleptic characteristics, clarity and sedimentation of the selected mother tinctures.
- To determine pH, specific gravity, weight per millilitre, total solids and alcohol content using standard laboratory procedures.
- To assess identity using TLC/HPTLC fingerprinting according to the applicable HPI monograph or a validated reference method.
- To compare batch-to-batch and manufacturer-wise consistency and determine the proportion of samples complying with the applicable quality specifications.
- To identify practical quality-control concerns relevant to post-market surveillance of homoeopathic mother tinctures.
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3. MATERIALS AND METHODS

3.1 Study design and setting

A cross-sectional, comparative laboratory study design was adopted. Retail samples were conceptualised as being procured from licensed homoeopathic pharmacies located across major commercial and residential zones of Bhopal, Madhya Pradesh. Laboratory evaluation was structured for a Department of Homoeopathic Pharmacy setting using pharmacopoeial and routine pharmaceutical quality-control procedures. No human participants, animals or clinical interventions were involved.

3.2 Sample size and sampling plan

A total of 30 retail samples were included. Five commonly marketed mother tinctures were selected. For each medicine, three manufacturers were coded as Brand A, Brand B and Brand C; two different batches from each manufacturer were included. Thus, each mother tincture contributed six samples (5 medicines × 3 brands × 2 batches = 30 samples). Manufacturer identity was masked in the analysis to keep the study focused on quality characteristics rather than commercial comparison.

Table 1. Sampling framework for the retail quality assessment

Mother tincture	Source/part commonly used	Code	Brands	Batches/brand	Total samples
Rauwolfia serpentina Q	Root	RS	A, B, C	2	6
Nux vomica Q	Seed	NV	A, B, C	2	6

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Andrographis paniculata Q	Whole plant	AP	A, B, C	2	6
Calendula officinalis Q	Flowering herb/flower	CO	A, B, C	2	6
Berberis vulgaris Q	Root/root bark	BV	A, B, C	2	6

3.3 Inclusion and exclusion criteria

Inclusion criteria were: sealed mother tincture packs bearing batch number and manufacturing details; products within labelled shelf life; products represented by two distinct batches where available; and products corresponding to official homoeopathic medicines. Exclusion criteria were: damaged or leaking packs, illegible labels, expired products, duplicate bottles from the same batch used as separate market samples, and products stored under visibly unsuitable retail conditions.

3.4 Physicochemical and identity tests

Testing was aligned with the applicable individual HPI monograph and general pharmacopoeial procedures. PCIM&H describes pharmacopoeial monographs as standards for identity, purity and strength, using physicochemical and instrumental methods as applicable [1,2]. Published standardisation studies of mother tinctures have used the same core parameters—organoleptic profile, sediment, pH, specific gravity or weight per millilitre, total solids, alcohol content and chromatographic fingerprinting [6,10-12].

Table 2. Quality-control parameters and analytical approach

Parameter	Procedure/Instrument	Expression	Quality interpretation
Organoleptic profile	Visual examination under uniform light; characteristic odour noted without prolonged inhalation	Colour, clarity, odour	Compared with monograph/expected characteristic profile
Sediment	Sample allowed to stand; bottle examined against contrasting background	Absent/Present	Visible persistent sediment treated as deviation unless specified
pH	Calibrated digital pH meter at room temperature	pH units	Compared with applicable monograph/reference range
Specific gravity	Pycnometer/specific gravity bottle at controlled temperature	Dimensionless	Compared with applicable monograph/reference value
Weight per mL	Mass of known volume using calibrated pycnometer or density vessel	g/mL	Compared with applicable monograph/reference range
Total solids	Measured aliquot evaporated, then dried to constant mass under	% w/v or as specified	Compared with applicable individual monograph

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	prescribed conditions		
Alcohol content	Distillation followed by specific-gravity/alcoholometric determination or validated equivalent	% v/v	Compared with HPI/labelled range; typically allowed within monograph tolerance
TLC/HPTLC identity	Silica gel plate and drug-specific mobile phase; visualization under daylight/UV and after derivatisation where required	Concordant/non-concordant fingerprint	Characteristic bands/Rf pattern compared with official or validated reference

3.5 Quality assurance

pH meter calibration was performed with appropriate standard buffers before testing. Volumetric glassware and density vessels were checked for cleanliness and integrity. Each quantitative measurement was planned in triplicate and the mean reading used for the sample-level result. Reagents were analytical grade. For TLC/HPTLC, plates were handled with clean forceps, the chamber was pre-saturated as required, and sample application and development distance were kept consistent. A reference or authenticated comparator was included whenever the monograph or validated method required one.

3.6 Data handling and statistical analysis

Sample-level results were summarized using mean, standard deviation and range. Complete compliance was defined as meeting all evaluated parameters applicable to the sample. Manufacturer-wise and medicine-wise compliance proportions were calculated as percentages. Because the principal purpose was pharmacopoeial conformity screening rather than hypothesis testing, descriptive statistics were emphasized. Where actual replicated laboratory data are available, one-way analysis of variance or an appropriate non-parametric test may additionally be applied to compare manufacturers for each medicine separately, with $p < 0.05$ considered statistically significant.

4. RESULTS

Thirty samples representing five mother tinctures, three coded manufacturers and two batches per manufacturer were included in the illustrative analysis. Twenty-six samples met all evaluated requirements, giving an overall complete-compliance proportion of 86.7%. TLC identity was concordant in all samples. Four samples demonstrated one or more physicochemical or visual deviations.

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Table 3. Overall physicochemical profile by mother tincture (n = 6 per medicine)

Mother tincture	pH	Specific gravity	Wt./mL (g)	Total solids	Alcohol (% v/v)	Compliant samples
Rauwolfia serpentina Q	6.02 ± 0.03	0.876 ± 0.002	0.874 ± 0.002	1.39 ± 0.04	75.5 ± 1.4	5/6
Nux vomica Q	5.71 ± 0.32	0.879 ± 0.002	0.877 ± 0.002	2.21 ± 0.04	76.5 ± 0.3	5/6
Andrographis paniculata Q	5.83 ± 0.03	0.906 ± 0.002	0.904 ± 0.002	2.75 ± 0.04	61.9 ± 0.3	6/6
Calendula officinalis Q	5.57 ± 0.03	0.952 ± 0.002	0.950 ± 0.002	1.95 ± 0.15	39.6 ± 1.2	5/6
Berberis vulgaris Q	5.31 ± 0.03	0.915 ± 0.002	0.913 ± 0.002	2.48 ± 0.04	60.5 ± 0.3	5/6

Table 4. Sample-wise physicochemical findings and overall conformity

Sample	pH	Spec. gravity	Wt./mL	Total solids	Alcohol %	Sediment/TLC	Overall status
RS-A1	5.96	0.873	0.871	1.44	76.6	Absent / Concordant	Complies
RS-A2	6.03	0.874	0.872	1.40	76.2	Absent / Concordant	Complies
RS-B1	6.04	0.876	0.874	1.34	75.6	Absent / Concordant	Complies
RS-B2	6.00	0.875	0.873	1.36	75.9	Absent / Concordant	Complies
RS-C1	6.07	0.878	0.876	1.42	76.3	Absent / Concordant	Complies
RS-C2	6.01	0.879	0.877	1.35	72.4	Absent / Concordant	Does not comply
NV-A1	5.50	0.876	0.874	2.26	77.1	Absent / Concordant	Complies
NV-A2	5.57	0.877	0.875	2.22	76.7	Absent / Concordant	Complies
NV-B1	5.58	0.879	0.877	2.16	76.1	Absent / Concordant	Complies
NV-B2	6.42	0.878	0.876	2.18	76.4	Absent / Concordant	Does not comply
NV-C1	5.61	0.881	0.879	2.24	76.8	Absent / Concordant	Complies
NV-C2	5.55	0.882	0.880	2.17	76.2	Absent / Concordant	Complies
AP-A1	5.77	0.903	0.901	2.80	62.4	Absent / Concordant	Complies
AP-A2	5.84	0.904	0.902	2.76	62.0	Absent / Concordant	Complies
AP-B1	5.85	0.906	0.904	2.70	61.4	Absent / Concordant	Complies
AP-B2	5.81	0.905	0.903	2.72	61.7	Absent / Concordant	Complies

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AP-C1	5.88	0.908	0.906	2.78	62.1	Absent / Concordant	Complies
AP-C2	5.82	0.909	0.907	2.71	61.5	Absent / Concordant	Complies
CO-A1	5.51	0.949	0.947	2.08	40.7	Absent / Concordant	Complies
CO-A2	5.58	0.950	0.948	2.04	40.3	Absent / Concordant	Complies
CO-B1	5.59	0.952	0.950	1.98	39.7	Absent / Concordant	Complies
CO-B2	5.55	0.951	0.949	2.00	40.0	Absent / Concordant	Complies
CO-C1	5.62	0.954	0.952	1.63	36.9	Absent / Concordant	Does not comply
CO-C2	5.56	0.955	0.953	1.99	39.8	Absent / Concordant	Complies
BV-A1	5.25	0.912	0.910	2.54	61.1	Absent / Concordant	Complies
BV-A2	5.32	0.913	0.911	2.50	60.7	Absent / Concordant	Complies
BV-B1	5.33	0.915	0.913	2.44	60.1	Absent / Concordant	Complies
BV-B2	5.29	0.914	0.912	2.46	60.4	Present / Concordant	Does not comply
BV-C1	5.36	0.917	0.915	2.52	60.8	Absent / Concordant	Complies
BV-C2	5.30	0.918	0.916	2.45	60.2	Absent / Concordant	Complies

Table 5. Summary of detected deviations

Sample code	Medicine	Observed deviation	Interpretation
RS-C2	Rauwolfia serpentina Q	Alcohol below reference range	Requires confirmation by repeat analysis and review against applicable HPI/label specification
NV-B2	Nux vomica Q	pH outside reference range	Requires confirmation by repeat analysis and review against applicable HPI/label specification
CO-C1	Calendula officinalis Q	Alcohol and total solids below reference range	Requires confirmation by repeat analysis and review against applicable HPI/label specification
BV-B2	Berberis vulgaris Q	Visible fine sediment after standing	Requires confirmation by repeat analysis and review against applicable HPI/label specification

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4.1 Manufacturer-wise conformity

Brand A showed complete compliance in 10/10 samples (100%). Brand B showed complete compliance in 8/10 samples (80%), while Brand C showed complete compliance in 8/10 samples (80%). These proportions should be interpreted as screening observations for the sampled batches only and not as definitive rankings of manufacturers.

4.2 Medicine-wise observations

Rauwolfia serpentina Q showed generally consistent density, pH and total-solids values, but one sample (RS-C2) had an alcohol value below the reference expectation. Published work on Rauvolfia/Rauwolfia mother tincture demonstrates that alcohol percentage, pH, weight per millilitre and total solids are useful routine indicators of manufacturing consistency [6,7].

Nux vomica Q samples were visually clear and TLC-concordant; however, NV-B2 showed an atypical pH and was therefore classified as non-compliant pending repeat confirmation. HPTLC fingerprinting of Nux vomica has previously been shown to be useful for comparing commercial products and for quantification of brucine as a marker [4].

Andrographis paniculata Q was the most uniform group in the illustrative dataset, with all six samples complying with the selected physicochemical and identity criteria. Earlier HPTLC work on commercial Andrographis mother tinctures found marked variation in andrographolide content between products despite successful chromatographic identification, highlighting why marker-based testing can add value beyond routine physical tests [5].

Calendula officinalis Q showed one clear deviation (CO-C1), with both reduced alcohol content and reduced total solids. These two parameters are directly relevant to extraction strength and non-volatile constituent yield, so simultaneous reduction would warrant investigation of batch preparation, evaporation, dilution or storage conditions. The remaining samples were consistent in appearance, pH and density.

Berberis vulgaris Q showed generally consistent physicochemical values, but BV-B2 developed visible fine sediment on standing. Persistent sediment may result from precipitation of extracted matter, storage-related changes or contamination and should trigger confirmatory examination, especially if the official monograph expects a clear preparation.

5. DISCUSSION

The present study provides a practical model for post-market pharmaceutical quality assessment of homoeopathic mother tinctures. The overall pattern—high conformity with a smaller number of batch-specific deviations—is plausible for regulated products while still demonstrating the value of retail surveillance. Importantly, the findings show why a single parameter is insufficient. A product may appear visually acceptable yet differ in alcohol content or pH, while another may meet physicochemical limits but require confirmation of chemical identity by TLC or HPTLC.

Alcohol content is a particularly informative test because hydroalcoholic extraction is fundamental to mother-tincture manufacture. The proportion of alcohol determines solvent polarity and influences the spectrum of plant constituents extracted. Regulatory requirements in India specifically require alcohol content and total solids to be determined and recorded for mother tinctures [3]. In a comparative study of Rauwolfia serpentina, Dwivedi et al. used

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physicochemical testing together with HPTLC and reported clear differences in reserpine content among marketed and in-house preparations [6]. Ghate et al. similarly used appearance, alcohol percentage, pH, weight per millilitre and total solids to compare tinctures prepared from wild and cultivated Rauvolfia roots [7].

Total solids complement alcohol testing by indicating the amount of non-volatile material extracted into the finished mother tincture. A low value may reflect weak extraction, excessive dilution, raw-material variation or process inconsistency, whereas an unusually high value may indicate concentrated extractive matter, suspended impurities or formulation differences. Therefore, the combined reduction in alcohol and total solids observed in the illustrative Calendula sample would be more concerning than a small isolated shift in one parameter and should prompt repeat testing and review of the relevant manufacturing batch record.

pH is another useful batch-consistency parameter. Although pH alone cannot establish identity or potency, a significant shift may reflect changes in plant constituents, solvent composition, degradation or contamination. Recent standardisation studies in homoeopathy continue to include pH together with specific gravity, total solids, UV-visible spectra and HPTLC, supporting its use as one component of a multidimensional quality profile [10,11].

Chromatographic identity testing strengthens the assessment because it examines the chemical pattern rather than only gross physical properties. Shanbhag and Jayaraman demonstrated the use of HPTLC for Nux vomica and Andrographis paniculata, while Jadhav et al. validated marker-based HPTLC for Toxicodendron pubescens using quercitrin and rutin [4,5,8]. More recently, Kumar et al. developed validated HPTLC fingerprints for 16 mother tinctures for which TLC standards were lacking, emphasizing continued expansion of analytical quality standards [9]. This progression supports the integration of routine physicochemical testing with chromatographic fingerprinting in teaching laboratories and quality-control facilities.

The 86.7% complete-compliance proportion in the model dataset should not be interpreted as a true estimate of the Bhopal market until actual samples are tested. Nevertheless, the study design is appropriate for identifying batch-specific concerns. Masking manufacturer names is also useful academically because it minimizes commercial bias and focuses interpretation on pharmaceutical quality. Any non-compliant screening result should be confirmed by repeat analysis, verification of instrument calibration, review of the exact HPI monograph and, where necessary, testing by an accredited or government laboratory before regulatory conclusions are made.

From the perspective of homoeopathic pharmacy, the main value of this work is methodological. It demonstrates that meaningful retail quality assessment can be performed using accessible laboratory parameters while still being anchored to official standards. The approach can be expanded in future by adding UV-visible spectral profiling, validated HPTLC densitometry, marker-compound quantification, microbial limit testing and elemental impurity analysis where indicated.

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6. LIMITATIONS

- The numerical findings presented in this draft are illustrative because raw experimental readings were not supplied; they must not be represented as observed results until replaced or verified.
- The proposed sample size of 30 is suitable for a departmental comparative study but does not represent every manufacturer or retail outlet in Bhopal.
- Physicochemical conformity cannot by itself establish therapeutic equivalence; chromatographic or marker-based assays may be required for deeper standardisation.
- Retail storage history before purchase may not be fully known and can influence alcohol loss, precipitation or colour changes.
- Brand coding prevents commercial inference and the study should not be used to rank manufacturers without a larger independently verified sampling programme.

7. CONCLUSION

A structured combination of organoleptic examination, sediment assessment, pH, specific gravity, weight per millilitre, total solids, alcohol content and TLC/HPTLC identity testing provides a practical and pharmacopoeially relevant framework for assessing the quality of homoeopathic mother tinctures sold through retail pharmacies. In the illustrative 30-sample dataset, most samples were consistent with applicable specifications, while a small number showed deviations in alcohol content, pH, total solids or sedimentation. These findings reinforce the importance of batch-wise quality control and periodic post-market surveillance. For a final publishable study, every reported value should be generated from documented laboratory testing and interpreted against the exact current HPI monograph for the corresponding mother tincture.

8. RECOMMENDATIONS

- Retail surveillance of mother tinctures should periodically include at least alcohol content, total solids, pH, density/weight per millilitre and identity testing.
- Non-conforming screening results should be repeated from the same bottle and, when possible, confirmed using another bottle from the same batch.
- HPTLC densitometry with suitable marker compounds should be added for medicines in which validated marker methods are available.
- Retailers should store mother tinctures tightly closed, protected from heat and direct sunlight, to minimize alcohol loss and physicochemical deterioration.
- Future Bhopal-based studies may include a larger number of manufacturers, more batches, seasonal sampling and accredited-laboratory confirmation.

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