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Assessing the shelf-life and stability of homoeopathic drugs beyond their labelled expiry dates: A systematic approach

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Abstract
Homoeopathy is seen as an efficient medical system that aims to restore health gently and reliably by following natural principles. Shelf-life refers to how long the active pharmaceutical ingredient in a finished product stays stable, as long as the medicine is stored under the environmental conditions listed on the packaging. Mother tinctures are the basic liquid extract of vegetable and animal sources, prepared by extracting raw materials into alcohol, water or a mix of both. The effectiveness of these tinctures depends upon certain reference parameters. The inclusion of expiration dates in homoeopathy is a recent development driven by the understanding that active principles, such as alkaloids degrades over time due to environmental factors. While health authorities apply standardised expiration rules to all homoeopathic products, a significant debate exists within the field. Many practitioners argue that ultra-diluted potencies remain therapeutically viable for decades if stored correctly. In contrast, "Mother tincture" and medicines with lower alcohol concentrations are more susceptible to deterioration, often showing signs of ageing within 5 years. These changes are primarily physicochemical, involving alcohol evaporation, increased moisture absorption, and a subtle shift in pH level.
"According to Hahnemann's Organon of Medicine, the integrity of the medicine is the physician's responsibility. A practitioner must use medicines of "unimpaired strength" to ensure the treatment is effective and reliable."

Keywords: Stability, shelf-life, expired medicine, homoeopathy, standardisation, quality control, H.P.I. parameter, regulatory protocol

Introduction

Lab analysis for standardisation: For assessing stability and shelf-life, various analytical methods are used.

A. Organoleptic Analysis

1) Changes in colour and odour.
2) Sediment formation.

B. Physicochemical Analysis

1) pH: In homoeopathic quality, pH is defined as the negative logarithm of hydrogen ion concentration. Monitoring pH allows manufacturers to detect internal chemical changes. A significant shift in pH often signals the degradation of active plant constituents (such as flavonoids or alkaloids) or the occurrence of hydrolysis, where moisture triggers a breakdown of the medicinal compounds.

The "Ageing Marker" As the mother tincture ages, environmental factors often lead to alcohol evaporation and an increase in moisture. This process typically causes the solution to become more acidic. Regulators normally view a deviation of more than 5% from the initial baseline as an indication of product instability. To ensure accuracy, measurements are conducted using a calibrated glass electrode system. This provides a precise quantification of acidity and alkalinity, ensuring the tincture remains within the specific range dictated by the H.P.I.

2) Alcohol content: The alcohol content(ethanol) test serves as the definitive metric for

assessing a product's shelf-life and chemical durability, rather than acting as a simple solvent. Ethanol functions as the primary stabilising medium that maintains the medicine's complex chemical integrity. A stable alcohol percentage is vital for keeping active phytochemicals, including resins and alkaloids, fully dissolved. This prevents "precipitation."

Preservative efficacy – Formulations maintaining high ethanol concentrations (70%-90%) which effectively neutralise microbial threats and shield plant-derived compounds from oxidative damage. The concentration of alcohol is directly proportional to the remedy's ability to resist environmental breakdown. Consequently, monitoring alcohol level is the most reliable way for regulators to determine if a medicine remains therapeutically viable.

Weight per millilitre (Wt. per ml) – In the evaluation of stability and shelf-life of mother tincture, Wt. per ml test serves as a physical indicator of "ageing." Because homoeopathic stability is tied to the liquid vehicle's integrity. Any shift in wt. per ml value indicates that the medicine's chemical composition is no longer identical to the original, manufactured state. A primary reason for the expiration of a mother tincture is the evaporation of ethanol. Since alcohol is lighter than water, an increase in weight per ml confirms that the preservative level has dropped. If the value exceeds the limit set by the Homoeopathic Pharmacopoeia of India, the medicine can no longer be guaranteed against microbial growth. A decrease in wt. per ml suggests that active medicinal solids have precipitated out of the liquid. In stability testing, this indicates that the "synergistic profile" has been lost, because the therapeutic constituents are no longer bioavailable in the solution. Fluctuations in density often reveal that a medicine has absorbed atmospheric moisture. This change is used by regulatory authorities like the Ministry of AYUSH to justify the 3-year retesting rule and the final 5-year expiry cap for tinctures, as moisture accelerates the decomposition of the drug.

3) **Total solids** – In the technical evaluation of shelf-life and stability, the Total solids test quantifies the non-volatile residue remaining after the evaporation of alcohol and water. In a homoeopathic pharmacy, this test is a vital diagnostic tool for determining whether the medicinal "essence" of a mother tincture has maintained its integrity or has degraded over time**.**

Total solids as a metric for stability of mother tincture – the Total solids represent the stable phytochemical markers. To remain compliant with the homoeopathic pharmacopoeia of India, this value must stay within a strictly defined range during stability studies. As a mother tincture approaches its decomposition, the concentration of the total solids in the liquid phase often decreases. This is a sign that active constituents have precipitated out of the solution and settled at the bottom of the container. Conversely, a rise in total solids can occur if the alcohol evaporates due to a defective seal, which signifies a failure in standardisation. Such a product is deemed unfit for use under good manufacturing practice (GMP) because it no longer matches the reference standard.

C. Chromatographic Analysis

1) **TLC analysis** - In the technical assessment of shelf-life and expiration, thin-layer chromatography (TLC) serves as the definitive "chemical fingerprinting" tool for stability. TLC analysis reveals specifically what has shifted at the molecular level.

Stability monitoring – during periodic trials, the tincture is re-examined. The disappearance of original bands or the emergence of new "degradation bands" provides clear evidence that the chemical markers have broken down.

2) **HPTLC/HPLC analysis –** Through HPTLC densitometry, the concentration of specific chemicals is measured precisely. A reduction in the area under the curve (AUC) exceeding 10% from the initial baseline provides the scientific justification for assigning or enforcing an expiry date.

Fingerprinting as a stability tool – In cases where a specific "active ingredient" cannot be isolated, the WHO allows the use of chromatographic fingerprinting (HPTLC/HPLC). A tincture is deemed stable if its pattern of bands or peaks remains consistent when compared to a fresh reference standard.

D. UV-VIS Spectroscopy

1) **Lambda max** - In the evaluation of pharmaceutical stability, lambda max (λ max) represents the specific wavelength at which a medicinal substance demonstrates peak light absorption. Measured via UV-Visible spectroscopy, this value functions as a molecular "signature." In homoeopathic quality control, any shift in the lambda max is a high-precision indicator of molecular breakdown of medicine. If a remedy degrades due to oxidation, pH fluctuations, or light exposure, the molecular framework of its active ingredients alters. This results in a shift of the lambda max to a different wavelength. In hyperchromic (increase) or hypochromic shift, the lambda max light remains constant; a significant reduction in the amount of light absorbed indicates that the concentration of active medicinal markers has diminished. While in a fresh, stable tincture, the absorption peaks are sharp and well-defined.

E. Phytochemical Analysis

The application of diverse chemical reagents in the phytochemical screening process confirmed that the sample contains several secondary metabolites, specifically phenols, tannins, alkaloids, and volatile oils.

Furthermore, establishing physicochemical constants such as ash value and other related metrics serves as a dependable method for verifying the identity, purity, and medicinal strength of the preparation.

Regulatory Guideline for Homoeopathic Medicine

1) **Indian statutory framework**

- **Schedule M-I (drugs and cosmetic rules, 1945):** This is the core legislative authority for homoeopathic good manufacturing practices (GMP). It originally instituted the "60-month rule", capping the maximum shelf-life for both tinctures and potencies at five years.
- **The 2017 regulatory shift:** Under notification G.S.R. 1380 (E), the Ministry of AYUSH modernised these rules. It removed the mandatory expiry date for high-potency dilutions, distinguishing them from chemical-heavy tinctures, which still require a 5-year limit.
- **H.P.I:** The homoeopathic pharmacopoeia of India remains the official benchmark for identity and purity, specifically regulating the ethanol concentration vital for maintaining product stability.

2) Quality and stability protocol

- **AYUSH Retesting mandate:** Manufacturers must follow a structured verification timeline: Three-year milestone: An initial re-evaluation of the mother tincture is required after 3 years.

Annual maintenance: following the 3-year mark, annual testing must confirm that alcohol levels, pH, and total solids remain within HPI specifications.

Global alignment (WHO & ICH): Quality control adheres to WHO standards for botanical materials, utilising chromatographic and testing. Furthermore, ICH guidelines (Q1A-Q1F) are used to conduct accelerated and real-time stability studies to scientifically validate shelf-life claims.

Conclusion

Despite its benefits, homoeopathy faces scrutiny regarding the consistency of its results and a perceived lack of rigorous standardisation. Because tinctures are made from raw materials, quality is different, monitored through physical and chemical testing, as well as chromatographic analysis to identify specific chemical markers. The concept of "expiry dates" is relatively new to the field of homoeopathy due to a historical lack of scientific data on the degradation of medicines.

Conflict of Interest

There are no conflicts of interest related to this study.

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