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Indian Standard for Globules used in Homoeopathy

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Abstract

This article aims to describe and critically examine the Indian Standard (IS 18947:2024) for globules used in Homoeopathy, outlining the technical specifications, testing methods, and significance for pharmaceutical quality assurance. The implications of the standard for manufacturers, quality control laboratories, consumers and regulatory bodies engaged in the production and evaluation of homoeopathic drugs are highlighted by presenting a consolidated view of the standard's scope and applications. This discussion underscores the continued importance of systematic standardization in ensuring the safety, consistency, and global credibility of homoeopathic medicinal products produced in India.

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DISCUSSION

Indian Standard for Globules used in Homoeopathy

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ABSTRACT

This article aims to describe and critically examine the Indian Standard (IS 18947:2024) for globules used in Homoeopathy, outlining the technical specifications, testing methods, and significance for pharmaceutical quality assurance. The implications of the standard for manufacturers, quality control laboratories, consumers and regulatory bodies engaged in the production and evaluation of homoeopathic drugs are highlighted by presenting a consolidated view of the standard's scope and applications. This discussion underscores the continued importance of systematic standardization in ensuring the safety, consistency, and global credibility of homoeopathic medicinal products produced in India.

Keywords: BIS standard, Globules, Homoeopathy, Pharmaceuticals, Quality control

Introduction

The homoeopathic medications are prepared and dispensed in different pharmaceutical forms. These include the liquid forms, such as dilutions, and the solid pharmaceutical forms, such as globules, powders, and tablets. The quality and uniformity of pharmaceutical starting materials for these dosage forms play a vital role in ensuring the safety, efficacy, and reproducibility of therapeutic products.

Among the various dosage forms used in Homoeopathy, globules are the most widely used form by homoeopaths for dispensing potentised medicines intended for internal use. Globules are small, spherical pellets, composed of sucrose or a combination of sucrose and lactose, which function as inert vehicles intended to absorb and retain homoeopathic dilutions. Inert globules are homogenous, regular, white and odourless, and have a sweet taste (Fig. 1). They are designated and marketed in India according to their size and dimension.

Medicated globules are obtained by impregnation of inert sugar globules with homoeopathic dilutions. Studies have reported that characteristics of aqueous high dilutions are preserved and are detectable in dissolved globules.[1] Therefore, these globules serve as vehicles for liquid dilutions, ensuring convenient administration, palatability, and stability of the homoeopathic medicines. Although homoeopathic pharmacopoeias present different methods and techniques devised for the impregnation of inert globules, the techniques must ensure the evenness of impregnation and integrity of the globules.[2]

Given their widespread use, the quality, purity, and uniformity of homoeopathic globules are essential to ensure the reproducibility and reliability of therapeutic preparations. In the absence of standardisation,

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Fig. 1. Depiction of globules evaluation and standardisation under the Indian Standard (IS 18947:2024).

variations in the raw materials, manufacturing process, or physical or chemical characteristics of globules can lead to inconsistencies in dosage and stability. Recognizing this need, the Bureau of Indian Standards (BIS), formulated a dedicated national standard to specify the parameters for the quality of globules used in Homoeopathy. This standard has been developed to harmonize homoeopathic pharmaceutical practices within India, aligning them with international quality norms, and ensuring the reliability of products dispensed to patients. The standard also supports regulatory mechanisms such as those implemented by the Pharmacopoeia Commission for Indian Medicine & Homoeopathy, which together contribute to maintaining the scientific and manufacturing integrity of homoeopathic medicines in the country.

Methodology adopted for standard formulation

The Homoeopathic Sectional Committee of the BIS undertook the task of setting specifications for sugar globules or pillules, used in Homoeopathy. The Indian Standard for globules was formulated through a consensus-driven method.

Expert group

The Homoeopathy Sectional Committee responsible for development of this standard consists of stakeholders from various sectors such as industry, government bodies, R&D organisations, academia, consumer organisations etc. This Committee constituted a specialised panel of five experts. These experts did thorough research and prepared the 'working draft' (WD) based on the inputs from the subject experts, review of literature, related national/ international standards and pharmacopoeias. The WD prepared by this group formed the 'preliminary draft' (p-draft).

Document synthesis

This p-draft was circulated among the Sectional Committee members for a period of 14 days. The feedbacks received were discussed, and relevant modifications were incorporated to form a Wide Circulation draft (WC-draft). This WC-draft was then issued for wider consultation to all the stakeholders and the general public, providing an opportunity for everyone to review and comment.

The comments received at this stage were examined and assessed by the experts in the working group and placed before the Sectional Committee for finalisation of the draft. The draft was then finalised after reaching a consensus which was then approved by the Committee.

Final Indian standard

The final document for the *'Globules for Use in Homoeopathy — Specification'*, finalised by the Homoeopathy Sectional Committee was then approved by the Ayush Division Council. The standard was notified by the BIS through Gazette notification CG-DL-E-04122024-259137, dated 29th November, 2024 and an amendment through Gazette notification CG-DL-E-31072025-265123 dated 24 July 2025. The amendment was issued with the vision to provide clarity regarding the procedures of a few test methods.

The published standard can be downloaded by registering at the official BIS website. [3]

Key aspects of IS 18947: 2024

To ensure the use of unadulterated and safe globules used for the dispensing of homoeopathic pharmaceutical preparations, the quality parameters for sugar globules used in Homoeopathy have been defined in this standard. The description and test methods, including packing and storage of pure sucrose globules come under the scope of this standard. The tests and parameters for the ingredients of globules, their physical and chemical characteristics, like dimensions, absorption, etc., shelf life and other parameters are defined to ensure the quality of globules for their intended use.

These quality parameters help to ensure that the safety and therapeutic effect of homoeopathic medicines is not diminished due to the nature of the vehicle material of globules.

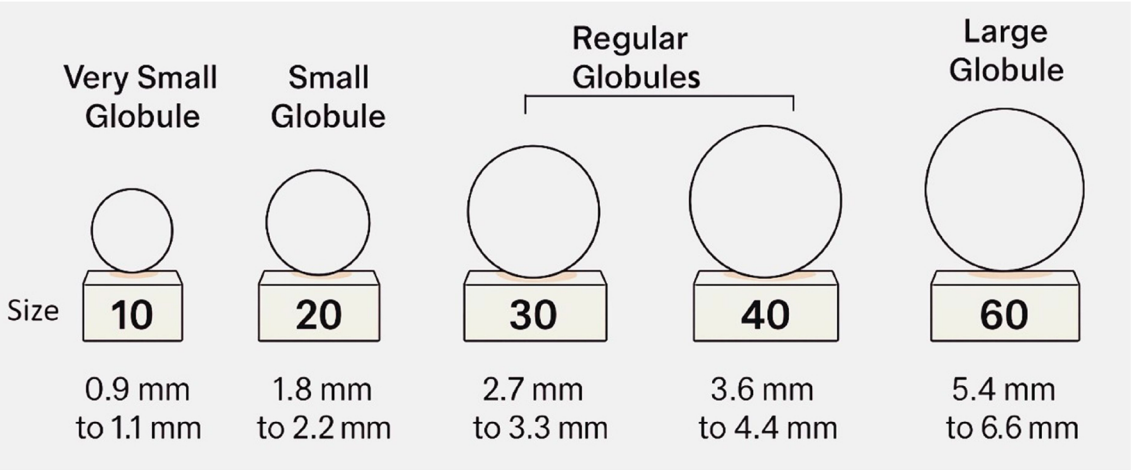

Fig. 2. Standard sizes of globules.

Physical properties

The shape, colour, taste, odour and friability of the globules are described as the basic requirements for globules. The distribution of the medicine is uniform over all globules if they have the same, reproducible surface area.

Size, weight and dimensions

This standard specifies the different types of globules with respect to the standard sizes and dimensions (Fig. 2). The clinicians use different sizes for dispensing medicines, with the size 30 and 40 being the most common. The size 10 globules are very small that are used for LM potencies. Other parameters that ensure uniform size, shape and weight are number of globules per gram, average size, fineness and uniformity of mass. These parameters ensure that the medicine is absorbed uniformly and each globule has the same medicinal effect. While the size of globules given in Fig. 2 is more common in Indian context, the 'Category' of globules described with respect to fineness is as per official Pharmacopoeias of other nations.

Content and ingredients

This Indian standard pertains to pure sucrose globules. The assay for testing the sucrose content in the globules has been described. Other chemical identification tests have also been given. Optical rotation value is characteristic for identifying the correct enantiomer, ensuring the therapeutic efficacy and safety of pharmaceutical material. Other parameters such as pH and loss on drying ensure the stability, solubility, appropriate moisture level, and absence of any acidic or alkaline impurities or microbial growth that may degrade the prepared globules during storage, affecting the therapeutic efficacy of the dosage form.

Purity

The purity of globules is further ensured by analysing the amount of residue on ignition. The tests for foreign matter that must not be present in quality globules have been described. Globules shall be free from any flavour, foreign matter like kaolin, chalk, talc, starch, animal dander, inorganic or any synthetic whitening agents.

The microbial contamination, specifically for the number of colony-forming units for total aerobic microbial count (TAMC), total combined yeasts/mould count (TYMC), *Staphylococcus aureus*, and *Pseudomonas aeruginosa* have been provided.

Porosity/Absorbance

The ability to uniformly absorb the homoeopathic medicine is the most significant property of the globules and depends on their porosity. For this purpose, the standard describes the permissible time required for the test solution of alcohol or methylene blue to be able to reach the core of impregnated globules. The uniformity of impregnation is further required to be tested by either of the two methods described, based on the visual indicator used, i.e. methylene blue test and the caffeine test.

Shelf life

The globules should remain stable, safe and devoid of any contamination over time when stored in clean and dry, non-reactive containers in

specific environmental conditions. These conditions are ensured at the industry level. However, to ensure that the quality of globules used by end users is uncompromised, a shelf life of 3 years is recommended, which is subject to data as per in-house stability studies of the manufacturer.

Discussion

The purity and quality of homoeopathic products govern the two important aspects, one is the success in homoeopathic prescribing and the second, the global acceptance of Homoeopathy. Modern scientific methods have helped set clear standards for the quality of homoeopathic pharmaceutical products, allowing any commercial sample to be checked as needed. Adhering to official homoeopathic pharmacopoeias and recognised guidelines ensures consistent quality, especially by defining specifications for raw materials and strictly following standardised manufacturing processes. The current regulatory framework and its requirements for homoeopathic products differ from country to country. The regulatory framework must be harmonised so that the difficulty arising out of disparate rules and regulations may not inhibit the overall development of Homoeopathy worldwide. [4]

Despite their long history of use and established role in homoeopathic practice, the quality parameters of globules, such as their physical, chemical, and microbiological attributes have lacked harmonized regulatory guidance. The Indian Standard IS 18947: 2024 is an attempt to address this gap, marking a significant advancement in the standardisation of globules used homoeopathic medicines in India. This standard has been developed based on the existing knowledge, official pharmacopoeias and the consensus of different stakeholders such as researchers, industry experts, practitioners and regulators.

The quality of globules influences the stability, potency, and safety of the homoeopathic medicinal product. In the absence of clear specifications, variability in raw material, manufacturing practices, and environmental conditions resulted in inconsistencies in globule quality. IS 18947: 2024 provides a scientifically grounded framework for ensuring uniformity and controlling these variables.

The introduction of IS 18947: 2024 reflects India's leadership in formalising quality standards for homoeopathic excipients, a domain where international consensus remains limited. The standard draws upon established principles from pharmaceutical quality systems and integrates them within the context of homoeopathic practice. It also encourages manufacturers to adopt validated analytical methods and controlled processing conditions to maintain product integrity. By defining measurable attributes and acceptance criteria, the standard facilitates consistency in production and quality evaluation across laboratories and manufacturing establishments. Further, this initiative aligns with India's broader commitment to strengthen quality assurance within the AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homoeopathy) sector, supporting the regulatory vision of the Ministry of AYUSH and national pharmacopeial authorities.

In addition to ensuring product reliability, the standard is intended to enhance consumer confidence and promote international acceptance of Indian homoeopathic preparations. As global trade and regulatory scrutiny intensify, the availability of a national standard serves not only as a quality benchmark but also as a reference for harmonization with future international or pharmacopeial standards. Consequently, IS 18947: 2024 contributes both to the scientific advancement of homoeopathic pharmaceutics and to the strengthening of India's regulatory infrastructure for traditional medicine systems.

This critical review of the background, framework, and technical aspects of IS 18947: 2024, emphasises its significance for manufacturers, regulators, and quality control laboratories involved in the production and evaluation of homoeopathic globules.

Acknowledgment

We acknowledge the members of the Working Group who contributed to the drafting of standard for globules: Dr Neeraj Gupta, Dr Mudita Arora, Dr Priyanka Motwani, Dr Binit Dwivedi, Ms Anamika Kotiya. All the members of the Homoeopathy Sectional Committee are also acknowledged for their valued inputs for the standard.

Funding statement

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Contribution details

Kumar Vivekanand: Critical review, Drafting of manuscript.
Daisy Katarmal: Drafting of manuscript.
Indra Gaurav Saxena: Drafting of manuscript.
Divya Taneja: Critical review.
Shrishti Dixit: Critical review.
Raj Kumar Manchanda: Critical review.

Conflict of interest

None.

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Editorial Note: This article is not peer-reviewed since it is an excerpt from a Govt. of India's gazetted document.

Norme indienne relative aux granules homéopathiques

Cet article vise à décrire et à analyser de manière critique la norme indienne (IS 18947: 2024) relative aux granules homéopathiques, en précisant les spécifications techniques, les méthodes d'essai et son importance pour l'assurance qualité pharmaceutique. Les implications de la norme pour les fabricants, les laboratoires de contrôle de la qualité et les organismes de réglementation impliqués dans la production et l'évaluation des médicaments homéopathiques sont mises en évidence par une présentation synthétique de son champ d'application. Cette analyse souligne l'importance continue d'une normalisation systématique pour garantir la sécurité, la constance et la crédibilité internationale des médicaments homéopathiques produits en Inde.

Indischer Standard für Globuli in der Homöopathie

Dieser Artikel beschreibt und analysiert kritisch den indischen Standard (IS 18947:2024) für Globuli in der Homöopathie. Er erläutert die technischen Spezifikationen, Prüfmethoden und die Bedeutung für die pharmazeutische Qualitätssicherung. Die Auswirkungen des Standards auf Hersteller, Qualitätskontrolllaboratorien und Aufsichtsbehörden, die an der Herstellung und Bewertung homöopathischer Arzneimittel beteiligt sind, werden durch eine zusammenfassende Darstellung des Anwendungsbereichs und der Einsatzmöglichkeiten des Standards verdeutlicht. Die Diskussion unterstreicht die anhaltende Bedeutung einer systematischen Standardisierung für die Sicherstellung der pharmazeutischen Qualität. Sicherheit, Konsistenz und globale Glaubwürdigkeit homöopathischer Arzneimittel aus Indien.

होम्योपैथी में इस्तेमाल होने वाली गोलियों (ग्लोब्यूल्स) के लिए भारतीय मानक

इस आर्टिकल का मकसद होम्योपैथी में इस्तेमाल होने वाली गोलियों (ग्लोब्यूल्स) के लिए इंडियन स्टैंडर्ड (IS 18947:2024) के बारे में जानना और उसकी गहराई से जांच करना है, जिसमें तकनीकी विवरण, जांचने के तरीके और फार्मास्यूटिकल गुणवत्ता जांचने के महत्व को बताया गया है। इस आर्टिकल द्वारा होम्योपैथिक दवाओं के निर्माण और मूल्यांकन में लगे उत्पादक, गुणवत्ता नियंत्रण प्रयोगशालाएं और नियामक निकाय के स्टैंडर्ड के दायरे और अनुपयोग का एक मिलाजुला नजरिया पेश किया गया है। यह चर्चा भारत में बनने वाली होम्योपैथिक दवाओं की सुरक्षा, स्थिरता और वैश्विक विश्वस्नियता के लिए सिस्टमैटिक स्टैंडर्डाइजेशन के महत्त्व को दर्शाती हैं |

Norma India para Glóbulos Utilizados en Homeopatía

Este artículo tiene como objetivo describir y examinar críticamente la Norma India (IS 18947: 2024) para glóbulos utilizados en homeopatía, describiendo las especificaciones técnicas, los métodos de prueba y su importancia para el aseguramiento de la calidad farmacéutica. Se destacan las implicaciones de la norma para fabricantes, laboratorios de control de calidad y organismos reguladores involucrados en la producción y evaluación de medicamentos homeopáticos, presentando una visión consolidada de su

alcance y aplicaciones. Este análisis subraya la importancia continua de la estandarización sistemática para garantizar la seguridad, la consistencia y la credibilidad global de los medicamentos homeopáticos producidos en la India

印度顺势疗法用药丸标准

本文旨在描述并批判性地审视印度顺势疗法用药丸标准（IS 18947: 2024），**概述其技**术规范、测试方法及其对药品质量保证的重要性。本文通过对标准范围和应用的综合阐述，重点强调了该标准对参与顺势疗法药物生产和评估的制造商、质量控制实验室和监管机构的影响。本文还强调了系统标准化对于确保印度生产的顺势疗法药品的安全性、一致性和全球信誉的持续重要性。