उत्पाद मानुयल
होम्योपैथी में प्रयोग हेतु ग्लोब्यूल्स- विनिर्देश
18947:2024 के अनुसार

PRODUCT MANUAL FOR
GLOBULES FOR USE IN HOMOEOPATHY - SPECIFICATION
ACCORDING TO IS 18947:2024

भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम 2018 की स्कीम-I के तहत यह उत्पाद मानुयल प्रमाणीकरणके प्रचलन मे रीति और पारदर्शिता के सुसंगता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों एवं लाइसेन्स धारियों द्वारा संदर्भ सामग्री के रूप मे उपयोग किया जाएगा। बीआईएस लाइसेन्स/प्रमाण पत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification license/certificate.

1	**उत्पाद** **Product**	:	IS 18947:2024
	शीर्षक **Title**	:	Globules For Use in Homoeopathy - Specification
	संशोधन संख्या **No. of Amendments**	:	1
2	**नमुनाकरण दिशा निर्देश** **Sampling Guidelines:**		
A	**कच्चा माल** **Raw material**	:	As per clause 4.1.4
B	**समूहिकरण दिशा निर्देश** **Grouping guidelines**	:	Sample of any size of Globules may be drawn and tested to cover all the sizes of Globules in the scope of licence
C	**नमूने का परिमाण** **Sample Size**	:	300 grams
D	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**	:	Name of the product: Standard Size of Globules as per Table 1: Classification of Globules According to their Mass as per Table 2:

			Note: Apart from the above, any other requirements/parameters may also be declared as per the standard, as applicable.
3	**परीक्षण उपकरणो की सूची** **List of Test Equipment**	:	कृपया Annex-A देखें Please refer ANNEX–A
4	**निरीक्षण व परीक्षण स्कीम** **Scheme of Inspection and Testing**	:	कृपया Annex-B देखें Please refer ANNEX–B
5	**एक दिन में संभावित परीक्षण** **Possible tests in a day:**	:	All tests except Microbial Contamination as per Cl 5.16
6	**लाइसेन्स का कार्यक्षेत्र / Scope of the Licence**:		
	IS 18947:2024 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स लनम्नलिलखत कायक्षेत्र के लिए प्रदान कया जाता है Licence is granted to use standard Mark as per IS 18947:2024 with the following scope:		
	उत्पाद का नाम Name of the product	Globules For Use in Homoeopathy	
	Standard Size	Size 10, 20, 30, 40 and 60	

ANNEX – A
List of test equipment

Sl. No	Tests used in with Clause Reference	Test Equipment
1	Solubility, Cl. 5.2.1	**Method as per Clause 5.2.1 of IS 18947** **Apparatus** Analytical balance (least count 0.01 g or better), 100 mL graduated measuring cylinder or volumetric, 250 mL glass beaker or conical flask for carrying out the dissolution, glass stirring rod or magnetic stirrer with a stir bar for continuous stirring, thermometer and watch glass. **Reagents** Distilled or deionized water
2	Solubility, Cl. 5.2.2	**Method as per Clause 5.2.2 of IS 18947** **Apparatus** Analytical balance (least count 0.01 g or better),100 mL graduated measuring cylinder or volumetric flask, a 250 mL glass beaker or conical flask, and a glass stirring rod or magnetic stirrer with a stir bar, watch glass and a thermometer. **Reagents** Ethyl alcohol of 90–95 percent (v/v) concentration, Distilled or deionized water
3	Number of Globules per Gram, Cl. 5.3	**Method as per Clause 5.3 of IS 18947** **Apparatus** Analytical balance (least count 0.001 g or better), petri dish or tray
4	Average Size, Cl. 5.4	**Method as per Clause 5.4 of IS 18947** **Apparatus** Vernier caliper (preferably with a least count of 0.02 mm or better), petri dish and forceps (optional)
5	Fineness, Cl. 5.5	**Method as per Clause 5.5 of IS 18947** **Apparatus** Standard test sieve set, mechanical sieve shaker (or manual sieving arrangement), analytical balance (least count 0.01 g or better)
6	Uniformity of Mass Cl 5.6	**Method as per Clause 5.6 of IS 18947** **Apparatus** Analytical balance with a readability of 0.1 mg (0.0001 g) or better, petri dish or sample tray, and forceps (optional)
7	Sucrose Content in Globules Cl. 5.7.1	**Polarimetry Method as per Annex-B of IS 18947** **Apparatus** Analytical balance, 100 mL volumetric, a glass stirring rod or magnetic stirrer, a vacuum filtration setup (comprising a Büchner funnel, filter flask, vacuum source and suitable filter paper), polarimeter fitted with a polarimeter tube of known length, and a drying oven together with a desiccator. **Reagents** Water R (reagent-grade water)

		HPLC Method as per Annex-B of IS 18947 **Apparatus** High-performance liquid chromatograph (HPLC) equipped with an isocratic solvent delivery system, manual injector, refractive index (RI) detector, and recording/computing integrator or chromatography data system, a 300 × 4 mm (i.d.) µ-Bondapak/Carbohydrate analytical column (or equivalent carbohydrate column), a test solution clarification kit or 0.45 µm solvent-resistant membrane filters for sample clarification, 10 µL HPLC syringes for sample injection, 50 mL and 100 mL volumetric flasks, small beaker, analytical balance, a magnetic stirrer with vacuum degassing arrangement, and standard laboratory glassware. **Reagents** LC-grade acetonitrile (CH_3CN), reagent-grade water (H_2O), the mobile phase consisting of acetonitrile and water (83:17, v/v), and analytical-grade fructose, glucose and sucrose for preparation of the sugar standard solution.
8	Optical Rotation, Cl. 5.8	**Method as per clause 6 of IS 15279** **Method For Determination of Polarization of Raw Sugar** **Apparatus** Visual or photoelectric polarimeter (saccharimeter) equipped with the International Sugar Scale and a visible light source at 589 nm (or 587 nm for quartz-wedge saccharimeters) with a reading accuracy of ±0.01 °Z, a 200 mm borosilicate glass polarizing tube (with or without thermostatic jacketing), a certified quartz control plate for calibration, an analytical balance readable to 0.0001 g, a thermometer readable to 0.1 °C, a water bath maintained at 20 ± 0.5 °C, an automatic dispenser or 50 mL safety burette fitted with a CO_2 absorption tube, Whatman No. 91 filter paper (or equivalent), a filtration apparatus consisting of a 100 mm stemless funnel, three 150 mL beakers and a 100 mm watch glass, a 1 L conical flask, a Büchner funnel with vacuum filtration setup (for preparation of lead acetate solution), and standard laboratory glassware. **Reagents** Reagent-grade water, concentrated or glacial acetic acid, nitrogen gas, and lead sub-acetate trihydrate [$Pb(OAc)_2 \cdot 3H_2O$] for preparation of the basic lead acetate solution.
9	Identification Tests Cl 5.9.1	**Method as per cl 5.9.1 of IS 18974** **Apparatus** Analytical balance for accurately weighing the sample, a 100 mL volumetric flask for preparing Solution Z, test tubes, test tube stand, graduated pipettes or micropipettes for measuring reagents, glass stirring rods, a beaker, a boiling water bath or hot plate/Bunsen burner for heating, a litmus paper for checking neutralization, and standard laboratory glassware **Reagents** Purified water, Tollens reagent, indole-3-acetic acid crystals, concentrated hydrochloric acid, 0.5 M sulphuric acid, 8% (m/v) sodium hydroxide solution, and alkaline cupric tartrate solution (SR).
10	pH, Cl 5.10	**Method as per cl 5.10 of IS 18974** **Apparatus**

		Analytical balance for accurately weighing the sample, a 100 mL volumetric flask for preparing the test solution, a glass beaker, a glass stirring rod or magnetic stirrer for dissolving the globules, and a calibrated pH meter fitted with a suitable glass electrode for pH measurement. **Reagents** Purified water, Buffer Solution
11	Loss on Drying Cl 5.11	**Method as per clause 4 of IS 15279** **Apparatus** Atmospheric pressure drying oven capable of maintaining a temperature of 105 ± 1 °C, a desiccator containing self-indicating silica gel, glass, platinum, nickel or aluminium dishes with fitting lids (6–11 cm diameter and 2–4 cm depth), a surface pattern dial thermometer or an equivalent electronic thermometer fitted with a surface probe, and an analytical balance with a readability of 0.1 mg (0.0001 g).
12	Impurities (Residue on Ignition) Cl. 5.12	**Method as per 5.12 of IS 18974** **Apparatus** Analytical balance (least count 0.1 mg or better), a silica, porcelain or platinum crucible, a muffle furnace capable of maintaining a temperature of 700 ± 25 °C, crucible tongs for handling the hot crucible, a desiccator containing a suitable desiccant for cooling the crucible before weighing, and standard laboratory glassware.
13	Foreign Matter Cl 5.13	**Method as per cl 5.13 of IS 18974** **Apparatus** Analytical balance for weighing the sample, a 100 mL volumetric flask for preparing 5% (w/v) Solution A from powdered globules, glass beakers, conical flasks, test tubes, graduated pipettes or droppers, glass stirring rod, a microscope capable of magnifications such as 40×, 100× and 400× for examination of animal dander, a clean glass microscope slide, a UV lamp capable of emitting light in the wavelength range of 254–365 nm for detection of whitening agents, and standard laboratory glassware. **Reagents** Purified water, dilute ammonia solution, dilute ammonium oxalate solution, dilute hydrochloric acid, ammonium carbonate solution, and iodine tincture solution.
14	Porosity, Cl. 5.14	**Method as per clause 5.14 of IS 18974** **Apparatus** Dropper or micropipette for dispensing the test solutions, a sharp stainless-steel blade or scalpel for cutting the globules, a stopwatch for measuring the impregnation time, a clean glass plate or petri dish for holding the globules during the test, and forceps (optional) for handling the globules. **Reagents** Dispensing alcohol and 0.1 percent methylene blue solution.
15	Uniformity of Impregnation Cl 5.15	**Method-A as per clause 5.15.1 of IS 18974** **Method A — Methylene Blue** **Apparatus**

		Analytical balance for accurate weighing of samples, a UV-Visible spectrophotometer capable of measuring absorbance at 665 nm, 1 000 mL, 100 mL and 25 mL volumetric flasks, graduated pipettes or micropipettes, glass beakers, glass stirring rod or magnetic stirrer, and standard laboratory glassware. **Reagents** Methylene blue reagent (R), ethanol (70% v/v) reagent (R), and water (R) **Method-B as per clause 5.15.2 of IS 18974** **Method B — Caffeine** **Apparatus** Analytical balance for accurate weighing of samples, a UV-Visible spectrophotometer capable of measuring absorbance at 273 nm, an ultrasonic bath (sonicator), a centrifuge, a 0.45 µm membrane filter with suitable filtration assembly, 50 mL and 100 mL volumetric flasks, graduated pipettes or micropipettes, glass beakers, a glass stirring rod, and standard laboratory glassware. **Reagents** Caffeine reagent (R), 70% (v/v) ethanol, and water (R).
16	Microbial Contamination Cl 5.16	**Method as per Annex-B of IS 18974** **Total Aerobic Microbial Count (TAMC)** **Apparatus** Analytical balance, laminar airflow cabinet or biosafety cabinet, autoclave, incubator maintained at 30–35 °C, sterile Petri dishes, sterile test tubes and conical flasks, micropipettes with sterile tips, sterile pipettes, colony counter, vortex mixer, pH meter, and standard microbiological laboratory glassware. **Reagents** Buffered sodium chloride-peptone solution (pH 7.0) or phosphate buffer solution (pH 7.2) as the diluent, Casein Soya Bean Digest Broth (TSB), Casein Soya Bean Digest Agar (TSA), purified water, and the prescribed reference microbial strains for growth promotion and suitability testing. **Method as per Annex-B of IS 18974** **Total Aerobic Microbial Count (TAMC)** **Apparatus** Analytical balance, laminar airflow cabinet or biosafety cabinet, autoclave, incubator, sterile Petri dishes, sterile test tubes, micropipettes with sterile tips, sterile pipettes, colony counter, and standard microbiological laboratory glassware. **Reagents** Buffered sodium chloride-peptone solution (pH 7.0) or phosphate buffer solution (pH 7.2), Sabouraud-Dextrose Agar (SDA), purified water, 0.05% polysorbate 80 (for preparation of *Aspergillus brasiliensis* spore suspension, where applicable), and the prescribed fungal reference strains. **Method as per Annex-B of IS 18974**

		Test for Escherichia coli **Apparatus** Analytical balance, laminar airflow cabinet or biosafety cabinet, autoclave, incubators maintained at 30–35 °C and 42–44 °C, sterile test tubes, sterile conical flasks, sterile Petri dishes, micropipettes with sterile tips, sterile inoculating loop, and standard microbiological laboratory glassware. **Reagents** Buffered sodium chloride-peptone solution (pH 7.0) or phosphate buffer solution (pH 7.2), Casein Soya Bean Digest Broth, MacConkey Broth, MacConkey Agar, purified water, and the prescribed reference strain of *Escherichia coli*. **Method as per Annex-B of IS 18974** **Test for Pseudomonas aeruginosa** **Apparatus** Analytical balance, laminar airflow cabinet or biosafety cabinet, autoclave, incubator maintained at 30–35 °C, sterile membrane filtration assembly (where applicable), sterile test tubes, sterile Petri dishes, micropipettes with sterile tips, sterile inoculating loop, and standard microbiological laboratory glassware. **Reagents** Buffered sodium chloride-peptone solution (pH 7.0) or phosphate buffer solution (pH 7.2), Casein Soya Bean Digest Broth, Cetrimide Agar, purified water, and the prescribed reference strain of *Pseudomonas aeruginosa*. **Method as per Annex-B of IS 18974** **Test for *Staphylococcus aureus*** **Apparatus** Analytical balance, laminar airflow cabinet or biosafety cabinet, autoclave, incubator maintained at 30–35 °C, sterile membrane filtration assembly (where applicable), sterile test tubes, sterile Petri dishes, micropipettes with sterile tips, sterile inoculating loop, and standard microbiological laboratory glassware **Reagents** Buffered sodium chloride-peptone solution (pH 7.0) or phosphate buffer solution (pH 7.2), Casein Soya Bean Digest Broth, Mannitol Salt Agar, purified water, and the prescribed reference strain of *Staphylococcus aureus*. **Method as per IS 5887 (Part 3/Sec 1): 2020** **Test for Salmonella spp.** **Apparatus** Autoclave, dry-heat oven, incubators capable of maintaining 34–38 °C and 37 ± 1 °C, water bath capable of maintaining 41.5 ± 1 °C, refrigerator and a freezer capable of maintaining −20 ± 5 °C, pH meter with an accuracy of ±0.1 pH unit; sterile Petri dishes of approximately 90 mm diameter, with large Petri dishes of approximately 140 mm diameter where required; sterile inoculating loops of 10 µL and 1 µL capacity and inoculating needles/wires, sterile

		graduated pipettes of 25 mL, 10 mL, 1 mL and 0.1 mL capacities and micropipettes/automatic pipettes, sterile tubes, bottles and flasks of appropriate capacity, test-tube racks/stands; a colony counter, where required, a Bunsen burner/spirit burner or suitable aseptic work arrangement, refrigerated storage facilities for prepared media and reagents, and a timer for monitoring incubation and reaction times. **Reagents** Buffered Peptone Water (BPW); Rappaport-Vassiliadis medium with soya (RVS broth) or Modified Semi-solid Rappaport-Vassiliadis (MSRV) agar, and Müller-Kauffmann tetrathionate-novobiocin (MKTTn) broth, Xylose Lysine Deoxycholate (XLD) agar and a second complementary selective solid medium for selective plating, Triple Sugar Iron (TSI) agar, urea agar and L-lysine decarboxylation (LDC) medium; saline solution for biochemical and serological testing, β-galactosidase detection reagent/system, toluene, tryptone/tryptophan medium and Kovacs reagent where the optional biochemical tests are performed; and polyvalent anti-O and anti-H Salmonella antisera, along with anti-Vi antiserum where applicable, for serological confirmation, Appropriate positive and negative control strains.
	Sulphated Ash Cl 5.17	**Method as per clause 11 of IS 15279** **Apparatus** Incineration dish made of platinum, silica, or any other material resistant to the test conditions with a capacity of 100–200 mL and a minimum useful surface area of 15 cm^2, an electric furnace capable of maintaining a temperature of 525 ± 25 °C, an electric hot plate, gas burner, or heating lamp for pre-incineration, a desiccator containing an efficient desiccant, a water bath capable of maintaining 60–70 °C, an analytical balance with a readability of 0.1 mg (0.0001 g), a glass stirring rod, and standard laboratory glassware. **Reagents** Sulphuric acid solution, prepared by carefully adding 100 mL of concentrated sulphuric acid (ρ20 = 1.83 g/mL) to 500 mL of water, hydrochloric acid solution

ANNEX B

SCHEME OF INSPECTION AND TESTING

1. **LABORATORY -** A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

   1.1. The manufacturer shall prepare a calibration plan for the test equipment.

2. **TEST RECORDS** – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. **PACKING, MARKING AND STORAGE**– The Standard Mark, as given in the Schedule of the licence, shall be printed on each container or printed on the label applied to it, as the case may be, provided always that the material in each container to which this mark is thus applied, conform to every requirement of the specification.

   3.1. Packing, marking and storage shall be done as per the provision of the Indian Standard. In addition, the following details shall be mentioned on each container legibly and indelibly:
   a) BIS website details i.e. – "For details of BIS certification please visit www.bis.gov.in".

4. **CONTROL UNIT** – For the purpose of this scheme, the quantity of Globules produced in a single day under similar manufacturing conditions from same raw material consignment shall constitute a control unit.

5. **LEVELS OF CONTROL -** The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

   5.1. All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. **RAW MATERIAL** – The raw material used for manufacturing the globules shall conform to the requirements given in Cl 4.1.4 of IS 18947:2024, and records maintained.

7. **REJECTIONS**–Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1
(Recommended Levels of Control by BIS - for Guidance Only)

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods**			**No. of Samples**	**Frequency**	**Remarks**
		Clause	**Reference**				
Cl. 4.1	Description	Cl. 4.1	IS 18947	R	1	Each Control unit	
Cl. 4.2	Size	Cl. 4.2	IS 18947	R	1	Each Control unit	
Cl. 5.2.1	Solubility	Cl 5.2.1	IS 18947	R	1	Each Control unit	
Cl. 5.2.2	Solubility	Cl 5.2.2	IS 18947	R	1	Each Control unit	
Cl. 5.3	Number of Globules per Gram	Cl. 5.3	IS 18947	R	1	Each Control unit	
Cl. 5.4	Average Size	Cl. 5.4	IS 18947	R	1	Each Control unit	
Cl. 5.5	Fineness	Cl. 5.5	IS 18947	R	1	Each Control unit	

Cl 5.6	Uniformity of Mass	Cl 5.6	IS 18947	R	1	Each Control unit	
Cl. 5.7.1	Sucrose Content in Globules	Cl. 5.7.1	IS 18947	S	1	Each consignment of raw material or Once in a Month whichever is earlier	
Cl. 5.8	Optical Rotation	Cl 6	IS 15279	S	1	Each consignment of raw material or Once in a Month whichever is earlier	
Cl 5.9.1	Identification Tests	Cl 5.9.1	IS 18947	S	1	Each consignment of raw material or Once in a Month whichever is earlier	
Cl 5.10	pH	Cl 5.10	IS 18947	R	1	Each Control unit	
Cl 5.11	Loss on Drying	Cl 4	IS 15279	R	1	Each Control unit	
Cl. 5.12	Impurities (Residue on Ignition)	Cl. 5.12	IS 18947	S	1	Each consignment of raw material or Once in a Month whichever is earlier	
Cl 5.13	Foreign Matter	Cl 5.13	IS 18947	R	1	Each Control unit	

Cl. 5.14	Porosity	Cl. 5.14	IS 18947	R	1	Each Control unit	
Cl 5.15	Uniformity of Impregnation	Cl 5.15	IS 18947	R	1	Each Control unit	
Cl 5.16	Total Aerobic Microbial Count (TAMC)	Annex-B	IS 18946	S	1	Once in a month	
	Total Combined Yeasts/ mould count (TYMC)	Annex-B	IS 18946	S	1	Once in a month	
	Test for Escherichia coli	Annex-B	IS 18946	S	1	Once in a month	
	Pseudomonas aeruginosa	Annex-B	IS 18946	S	1	Once in a month	
	Staphylococcus aureus	Annex-B	IS 18946	S	1	Once in a month	
	Salmonella spp.	-	IS 5887 (Part 3/Sec 1): 2020	S	1	Once in a month	
Cl 5.17	Sulphated Ash	Cl 11	IS 15279	S	1	Each consignment of raw material or Once in a Month whichever is earlier	

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Subcontracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.