

भारत सरकार
आयुष मंत्रालय
भारतीय चिकित्सा एवं होम्योपैथी भेषज संहिता आयोग
(भारतीय चिकित्सा एवं होम्योपैथी केन्द्रीय औषधि प्रयोगशाला)
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सत्यमेव जयते

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सूचना

तीसरे वैज्ञानिक सलाहकार बोर्ड सिफारिशों के अनुसार, ग्लोब्यूल्स एवं सैकरम लैक्टिस की एचपीआई मोनोग्राफ में माइक्रोबियल सीमाएं जोड़कर संशोधन किया गया है, जो हितधारकों की टिप्पणियों/सुझावों को 05-09-2024, शाम 5.30 बजे तक आमंत्रित करने के लिए अनुलग्नक के रूप में संलग्न है। टिप्पणियाँ/सुझाव निर्धारित समय अवधि के भीतर dir.pcimh-ayush@gov.in पर ईमेल के माध्यम से भेजे जा सकते हैं।

NOTICE

As per the recommendations of 3rd Scientific Advisory Board, Globules and *Saccharum Lactis*, HPI monographs amended by adding Microbial limits hereby enclosed as annexure for inviting stakeholders comments/suggestions by 05-09-2024, 5.30 pm. Comments/suggestions may sent through email to dir.pcimh-ayush@gov.in within the prescribed time period.

भवदीय


21/8/24
(डॉ. रमन मोहन सिंह)
निदेशक

संलग्न: A/a

SACCHARUM LACTIS

(Sac. lac.)

Chemical symbol	: C ₁₂ H ₂₂ O ₁₁ H ₂ O	Mol. wt.: 360.30
Common names	: Sugar of milk, Lactose, Lactose monohydrate	
Description	: A white, crystalline powder; odour less; taste slightly sweet. It is soluble in 5 parts of water, more soluble in hot water; very slightly soluble in <i>alcohol</i> ; particularly insoluble in <i>chloroform</i> and in <i>ether</i> . It may be obtained from the whey of milk.	
Identification	: a) When heated, it melts, swells and burns, evolving an odour of burnt sugar, leaving a bulky carbonaceous residue. (b) When heated with solution of <i>potassium cupri-tartrate</i> (Fehling's A+B Solution) a copious precipitate of <i>cuprous oxide</i> is formed.	
Specific optical rotation	: + 54.4° to +55.9° Dissolve 10.0 g in 80 ml water, heat at 50°. Cool it and add 0.2 ml of <i>dilute ammonia</i> . Allow to stand for 30 min. and dilute to 100 ml with <i>water</i> .	
Test of steroid	: Carry out TLC method for steroid No violet colored spot shall appear.	
Acidity	: 5.0 g dissolved in 50 ml of freshly boiled <i>water</i> , requires for neutralisation not more than 0.5 ml of 0.1 N <i>sodium hydroxide</i> , <i>phenolphthalein solution</i> being used as an indicator.	
Clarity, colour and odour of solution	: Dissolve 3.0 g in 10 ml of boiling <i>water</i> ; the solution is clear, colour less and odour less.	
Arsenic	: Not more than 1 part per million.	
Heavy metals	: Not more than 5 parts per million.	
Copper	: Dissolve 2 g in 20 ml of <i>water</i> , add 1 ml of <i>dilute hydrochloric acid</i> and 10 ml of <i>solution of hydrogen sulphide</i> ; no colour is produced.	
More soluble sugars	: Shake 5.0 g with 20 ml of <i>alcohol</i> (90 percent) for ten minutes, filter, evaporate 10 ml of the filtrate to dryness and dry at 105°, the residue weighs not more than 7 mg.	
Sulphated ash	: Not more than 0.1 percent.	
Water	: 4.5 to 5.5 percent, determined on 0.5 g in a mixture of 1 ml of <i>formamide</i> and 2 ml of <i>methanol</i> .	
Microbial limits	: Total Aerobic Microbial Count (TAMC) 10 ² CFU/g. Absence of <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Escherichia coli</i> and <i>Salmonella spp.</i>	
Storage	: Preserve in a well-closed container, protected from moisture	
Preparation	: Used as a vehicle.	

Globules

Globules are prepared from pure *cane sugar* (pharmaceutical grade of cane sugar/sucrose). It is sometimes made with 80 percent *sucrose* and 20 percent *lactose*.

1. **Description** : White colored, of uniform size.
2. **Size** : Claimed size normally designated as numbers (10, 15, 20, 25, 30, 40, 50, 80).
Lay ten globules in close contact with each other, measure the space so occupied in millimeters by a suitable Vernier Calliper and designate the measure as numbers. Permitted variation ± 10 percent.
Shape of globules must be perfectly globular; the diagonal diameters shall not vary more than 10 percent between them.
3. **Uniformity of mass**: Weigh 20 globules and determine average weight. Weigh individually 20 globules taken and determine the individual weight. Not more than 2 of the individual weight deviate from the average weight by more than 10 percent and none deviate more than 20 percent.
4. **Solubility** : Freely soluble in *water*.
5. **Sugar contents** : Not less than 99 percent of the claimed amount.
6. **Foreign matters** : Globules must be free from the following substances :
(a) Flavour (b) Starch (c) Glucose (d) Glycerine (e) Talc (f) Chalk (g) Kaolin (h)Antioxidants (i) Inorganic and synthetic whitening agents.
7. **Porosity** : Must be capable of impregnation as evidenced by capacity to absorb 0.1 percent, *methylene blue solution* to the center of the sphere, within 30 seconds (cut by a blade to observe)
8. **Loss on drying**: Not more than 5.0 percent.
9. **Sulfated ash** : Not more than 0.2 percent.
- 10 **Microbial limits**: Total Aerobic Microbial Count (TAMC) 10^2 CFU/g. Absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli* and *Salmonella spp.*