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MANUGEL LBA-SODIUM ALGINATE

DESCRIPTION

MANUGEL LBA (Ph. Eur) is a low viscosity, pure sodium alginate suitable for use in pharmaceutical products.

DETAILED REQUIREMENTS

1. Viscosity (10% Solution)	300-700 mPa.s (cP)
2. pH (1% Solution)	5.0-7.5
3. Loss on Drying	not greater than 15%
4. Particle Size	at least 98% through 355 µm
	at least 80% through 250 µm
5. (a) Appearance	Cream to light brown powder
(b) Powder Colour	not less than 38
6. Sulphated Ash (on dried solids basis)	30-36%
7. Calcium	not greater than 0.5%
8. Chloride	not greater than 1.0%
9. Total Heavy Metals	not greater than 20 mg/kg (ppm)
10. Lead (Pb)	not greater than 5 mg/kg (ppm)
11. Arsenic (As)	not greater than 2 mg/kg (ppm)
12. Copper (Cu)	not greater than 10 mg/kg (ppm)
13. Zinc (Zn)	not greater than 10 mg/kg (ppm)
14. Mercury (Hg)	not greater than 0.5 mg/kg (ppm)
15. Cadmium (Cd)	not greater than 0.5 mg/kg (ppm)
16. Microbiological Limits	
Bacteria	not greater than 5000 cfu/g
(total viable mesophilic aerobic count)	
Yeast & Mould	not greater than 200 cfu/g
Coliform	negative by MPN
E. coli	absent by Ph Eur test.
Salmonella	absent in 25 g

INGREDIENT

Sodium alginate Ph. Eur. CAS : 9005-38-3

REGULATORY COMPLIANCE

European Pharmacopoeia

Generally recognised as safe (GRAS) in accordance with 21 CFR 184.1724

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QUALITY SYSTEM

MANUGEL LBA (Ph. Eur) is manufactured according to a Quality System registered to ISO9001.

PACKAGING

MANUGEL LBA (Ph. Eur) is packaged in 25 kg multi-ply paper sacks fitted with polyethylene liner or equivalent. All packaging materials comply with relevant UK, EC and United States food contact legislation.

STORAGE

Packages should be kept sealed and stored in a cool, dry place.

METHODS OF TESTING (Full details of test methods are available on request)

1. **Viscosity (10% Solution)**

Prepare a 10% solution of product by pouring 450 g of deonised water at 20 degrees C into a 600 ml beaker. Add 50 g of product slowly whilst stirring the solution with an electric stirrer fitted with a propeller-type metal paddle. Stir for 2 hours at 800 rpm then adjust the temperature to 20 degrees C. Measure the viscosity immediately using an RV model of the Brookfield1 viscometer at 20 rpm with spindle 3 at 20 degrees C.

2. **pH (1% Solution)**

Measure the pH of a 1% solution at 20 degrees C using a pH meter.

3. **Loss on Drying**

Spread 5-10 g product evenly on a predried tared watch glass and weigh accurately. Dry in an oven at 105 + 1 degrees C for four hours. Cool in a desiccator and re-weigh.

4. **Particle Size**

Sieve 10 g product on the specified British Standard Screens (200 mm diameter) for three minutes each screen using an Alpine2 Air Jet Sieve. Use the finest mesh sieve first and progress to the coarsest mesh. Record the weight of product remaining on each screen and calculate the percentage which passes through each specified screen.

5. **Powder Colour**

Place powder in an optically flat Photovolt cuvette to a depth of 2 cm. Do not shake or tap. Using a green tristimulus filter, measure the powder colour on a Photovolt3 reflectometer standardised against a white enamel standard of 75% reflectance.

6. **Sulphated Ash**

Use the procedure given in the current edition of the European Pharmacopoeia.

7. **Calcium**

Calcium may be determined by atomic absorption techniques or by titration.

8. **Chloride**

Use the method given in the current edition of the European Pharmacopoeia.

9. **Total Heavy Metals**

Use the method given in the current edition of the European Pharmacopoeia.

10-15. **Lead, Arsenic, Copper, Zinc, Mercury and Cadmium**

These metals may be determined by atomic absorption techniques.

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16. **Microbiological Limits**

For bacteria (TVMAC), and E coli, follow the procedures as given for microbial limit tests in the current edition of the European Pharmacopoeia. For, salmonella, and yeast & mould, follow the procedures given in the current edition of the United States Pharmacopoeia, or the European Pharmacopoeia. Method for coliform is available on request. For bacteria, plate out 1 ml of 1% solution and incubate for 5 days at 30-35 degrees C. For yeast and mould plate out 1ml of 1% solution on acidified potato dextrose agar and incubate for 5 days at 20-25 degrees C. Express results as colony forming units (c.f.u.) per gram.