

Compositional Guideline for Calcified Lithothamnion species

Name of the ingredient

Calcified Lithothamnion species (AAN) and Calcified Lithothamnion tophiforme (AAN)

Definition of the ingredient

The substance is the skeletal deposits of *Lithothamnion* spp. (*L. corallioides*, *L. tophiforme*) sourced from the Atlantic Ocean. It is washed, dried and milled.

For the ingredient 'Calcified Lithothamnion tophiforme':

The substance is the skeletal deposits of Lithothamnion tophiforme sourced from Arnarfjordur in Iceland. It is washed, bleached, dried and milled.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Fine off-white powder
Odour	Organoleptic	Odourless
Characteristics		
Solubility	BP (General notices)	Practically insoluble in water
Ash	FCC	NLT 90 % w/w
Loss on drying	FCC	NMT 5 % w/w
Identification		
Calcium	ICP-OES	Complies

Test	Method reference	Acceptance criteria
Magnesium	ICP-OES	Complies
Carbonates	Ph Eur method 2.3.1	Complies
Assay		
Calcium	ICP-OES	NLT 32 % w/w
Magnesium	ICP-OES	NLT 2.2 % w/w
Carbon	ICP-OES	11 – 15 % w/w

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Lead	ICP-OES	NMT 1 ppm
Arsenic	ICP-OES	NMT 1.5 ppm
Cadmium	ICP-OES	NMT 1 ppm
Mercury	ICP-OES	NMT 0.1 ppm
Bromides	ICP-OES	NMT 10 ppm
Microbiology		
<p>While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is subject to a legally binding set of criteria. The Therapeutic Goods Order No. 100 <i>'Microbiological Standards for Medicines'</i> mandates that any finished product that contains the ingredient, alone or in combination with other ingredients, must comply with the microbial acceptance criteria set by Clause 11 of the Order.</p>		

Key to abbreviations:

BP = British Pharmacopoeia

Ph Eur = European Pharmacopoeia

FCC = Food Chemical Codex

NLT = Not less than

NMT = Not more than

ICP-OES = Inductively coupled plasma optical emission spectrometry