Australian Government
Department of Health
Therapeutic Goods Administration

Compositional Guideline for Alginate-konjac-xanthan polysaccharide complex

Name of the ingredient

Alginate-konjac-xanthan polysaccharide complex (AAN)

Definition of the ingredient

Alginate-konjac-xanthan polysaccharide complex is a polysaccharide complex resulting from the combination of konjac flour (70%), xanthan gum (17%) and sodium alginate (13%) in a fluidised bed reactor using heat and water followed by granulation.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Off-white to light tan granular powder
Odour	Organoleptic	Characteristic
Characteristics		
Loss on drying (135 °C, 6 h)	FCC10, Appendix IIc	Not more than 10 % w/w
Identification		
Absence of konjac flour	FCC10	Conforms
Absence of sodium alginate	FCC10	Conforms
Absence of xanthan gum	FCC10	Conforms
Viscosimetric characterisation	FCC10	Conforms

Test	Method reference	Acceptance criteria
Sodium	USP<191>	Positive
IR	USP<197>	Conforms with authenticated reference material/IR spectrum
Assay		
Viscosity over time	FCC10	Viscosity at 10 min: 800 – 10 900 cP Viscosity at 60 min: 16 400 – 42 200 cP Viscosity at 120 min: 22 700 – 45 000 cP

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual Solvents	BP 2016 (Appendix VIII L)	Meets the requirements of the BP
Incidental metals and non-metals		
While ingredient manufacturers are encouraged to include limits for Incidental metals and non-metals, it is the product into which those substances are formulated that contains the ingredient, alone or in combination with other ingredients, must comply with the acceptance criteria set in the United States Pharmacopeia - National Formulary (USP-NF) general chapter '<2232> Elemental Contaminants in Dietary Supplements'. When testing is performed at the raw material stage, calculation of the total daily exposure in the finished product should be performed. This calculation is based on the quantity of each ingredient present in the product, the maximum potential contamination given the proposed limits for each raw material and the daily dose of the product.		
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide Residues	USP <561>	Complies
Microbiology		

Test	Method reference	Acceptance criteria
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. 77 *'Microbiological Standards for Medicines'* 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 9 of the Order.		

Key to abbreviations:

BP = British Pharmacopoeia

FCC = Food Chemical Codex

IR = Infrared spectrophotometry

USP = United States Pharmacopoeia