Compositional Guideline for Poliglusam derived from *Aspergillus niger*

Name of the ingredient

Poliglusam derived from *Aspergillus niger* (AAN)

Synonym: Chitosan derived from *Aspergillus niger*

Definition of the ingredient

Poliglusam (2-Amino-2-deoxy-poly-D-glucosamine) is an insoluble, non-digestible fibre preparation derived from the cell walls of non-genetically modified *Aspergillus niger* mycelium. Poliglusam derived from *Aspergillus niger* contains not more than 15% beta-glucan.

Molecular formula: $(C_6H_{11}NO_4)_n$, $(C_6H_{10}O_5)_n$

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Fine free-flowing powder
Colour	Visual	Off-white to slightly brownish
Odour	Organoleptic	Odourless
Characteristics		
Loss on drying	Ph Eur 2.2.32	Not more than 10 % w/w
Viscosity 1% in acetic acid 1%	Ph Eur 2.2.10	2.5-15 mPa.s
Degree of acetylation	Ph Eur 2.2.20	0 to 30 mol%
Tapped density	Ph Eur 2.9.34	0.7-1.0 g/cm^3
Identification		
Chitosan	Fourier Transform Infrared Spectrum (Ph Eur 2.2.24)	Matches spectrum of authenticated Ph Eur

Test	Method reference	Acceptance criteria
		Reference standard
Assay		
Chitosan	Content determined by calculation	Not less than 80% w/w
Glucan	Ph Eur 2.2.25	Not more than 15% w/w

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
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.		
Other organic or inorganic impurities or toxins		
Ash	Ph Eur 2.4.16	Not more than 3 % w/w
Protein	Derivatisation and reaction with ninhydrin prior to analysis according to Ph Eur 2.2.25	Not more than 2 % w/w
Aflatoxin B1	Samples are extracted in an acetonitrile/water mixture, and the filtered extract is purified on an imunoaffinity column and then analysed by LC/MS/MS. [1, 2]	Not more than 0.5 $\mu g.kg^{-1}$
Aflatoxin B2		Not more than 0.5 $\mu g.kg^{-1}$
Aflatoxin G1		Not more than 0.5 $\mu g.kg^{-1}$
Aflatoxin G2		Not more than 1 $\mu g.kg^{-1}$

Test	Method reference	Acceptance criteria
Ochratoxin A		Not more than 1 μg.kg^{-1}
Fumonisin B1	Samples are extracted by a methanol/water/acetonitrile mixture and the filtered extract is purified on an immunoaffinity column. Analysis is then conducted using LC/MS/MS against ^{13}C-internal standards.[3]	Not more than 100 μg.kg^{-1}
Fumonisin B2		Not more than 100 μg.kg^{-1}
Microbiology		
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.		
Notes		
[1] Methods derived from those described in Krska, R. (1998), Journal of Chromatography A, 815 (1), 49-57. [2] Methods derived from Biselli, Hartig, Wegner & Hummert (2005), LC GC Europe, 20 (2), 20-32. [3] Method based on NF EN 14352 European norm- December 2004.		

Key to abbreviations:

HPLC = High-pressure liquid chromatography

LC/MS/MS = Liquid Chromatography-Tandem Mass Spectrometry

Ph Eur = European Pharmacopoeia