Australian Government
Department of Health
Therapeutic Goods Administration

Compositional Guideline for chicken comb extract

Name of the ingredient

Chicken comb extract

Definition of the ingredient

The substance is extracted from Chicken comb (*Gallus gallus* or rooster comb) by mild enzymatic hydrolysis followed by filtration, concentration and precipitation. Chicken combs are collected from poultry that are fit for human consumption.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Appearance	Visual	White or almost white hygroscopic powder
pH	Ph. Eur. 2.2.3	5.0 – 8.5
Loss on drying	Ph. Eur. 2.2.32	Not more than 10%
Nitrogen	Ph. Eur. 2.5.9	Not more than 8%
Chloride	Ph. Eur. 2.4.4	Not more than 1%
FT-IR (Sodium hyaluronate)	Ph. Eur. 2.2.24.	Complies with Ph. Eur. Reference spectrum of sodium hyaluronate
Sodium Hyaluronate	Ph. Eur. 1472	pink colour solution
Chondroitin Sulphate A and Dermatan Sulphate (Chondroitin Sulphate B)	Capillary electrophoresis	Retention time should be consistent with the reference standard of

Test	Method reference	Acceptance criteria
		Dermatan.
Assay		
Sodium Hyaluronate	Ph. Eur. 1472	60-75%
Chondroitin Sulphate A and Dermatan Sulphate (Chondroitin Sulphate B)	Capillary electrophoresis (Malavaki et al., 2008) Ph. Eur. 2.2.47	≤ 25%
Protein	Ph. Eur. Method 2.5.33 (Appendix VIII P. Total Protein)	10-25%

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Methanol	Ph. Eur. method 2.4.24 *(Gas chromatography (Ph. Eur. Method 2.2.28) with appropriate validated method)*	*Complies*
Ethanol	Ph. Eur. method 2.4.24 *(Gas chromatography (Ph. Eur. Method 2.2.28) with appropriate validated method)*	*Complies*
Acetone	Ph. Eur. method 2.4.24 *(Gas chromatography (Ph. Eur. Method 2.2.28) with appropriate validated method)*	*Complies*
Incidental metals and non-metals		

Test	Method reference	Acceptance criteria
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, which must comply with the acceptance criteria set in the United States Pharmacopoeia – National Formulary (USP-NF) general chapter '<2232> Elemental Contaminants in Dietary Supplements'.		
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticides	Ph. Eur. method 2.8.13	complies
Antibiotic residues	LC MS/MS	Complies with Australia New Zealand Food Standards Code, Standard 1.4.2 (Schedule 20 – maximum residue limits for chicken meat)
Other organic or inorganic impurities or toxins		
Dioxins	EPA method 1613	Not more than 2.0 pg/g
Dioxins and PCBs		Not more than 4.0 pg/g
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.		

Key to abbreviations:

BP = British Pharmacopoeia

HPLC = High-pressure liquid chromatography

IR = Infrared spectrophotometry

Ph. Eur. = European Pharmacopoeia

USP = United States Pharmacopoeia

pg = picogram

LC MS/MS = Liquid chromatography coupled with 2 mass analysers