Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Alanylglutamine

Name of the ingredient

Alanylglutamine (AAN)

Definition of the ingredient

N(2)-L-alanyl-L-glutamine

Molecular formula: $C_8H_{15}N_3O_4$

Molecular mass: 217.2

CAS Number: 39537-23-0

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White crystalline powder
Characteristics		
Solubility	BP General Notices	Very soluble in water
Appearance of solution (5% w/v in water)	Ph Eur methods 2.2.1 and 2.2.2 (Method II)	Clear and colourless
pH (1M aqueous solution)	Ph Eur method 2.2.3	5.4 – 6.0
Loss on drying (105°C/3 hr)	Ph Eur method 2.2.32	Not more than 0.5% w/w

Test	Method reference	Acceptance criteria
Identification		
IR spectroscopy	Ph. Eur. method 2.2.24	Complies with authenticated reference material.
Specific optical rotation (dry, 10 % w/v in water)	Ph Eur method 2.2.7	+ 9.0° to +11.0°
Assay		
Assay	Titration	98.0 – 102.0% w/w, on dried basis

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual solvents	Ph Eur method 2.4.24 and BP Appendix SC IV D	Complies
Incidental metals and non-metals		
Heavy metals (as lead)	Ph. Eur. method 2.4.8	Not more than 5 ppm
Arsenic	Ph. Eur. method 2.4.2	Not more than 1 ppm
Other organic or inorganic impurities or toxins		
Ammonium	Ph. Eur. method 2.4.1	Not more than 0.02% w/w
Chlorides	Ph. Eur. method 2.4.4	Not more than 0.02% w/w
Sulphates	Ph. Eur. method 2.4.13	Not more than 0.02% w/w
Sulphated ash	Ph. Eur. method 2.4.14	Not more than 0.1% w/w
Related substances	HPLC	Any individual impurity not more than 0.15%w/w.

Test	Method reference	Acceptance criteria
		Total impurities not more than 0.5%w/w
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-performance liquid chromatography

IR = Infrared spectrophotometry

Ph Eur = European Pharmacopoeia