



Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Dimethylglycine hydrochloride

Name of the ingredient

Dimethylglycine hydrochloride (AAN)

Definition of the ingredient

Molecular formula: $C_4H_9NO_2 \cdot HCl$

CAS Number: 2491-06-7

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White crystalline powder
Characteristics		
Solubility	BP (General notice)	Freely soluble in water and methanol
Sulfated ash	BP (Appendix IX A)	Not more than 0.1% w/w
Identification		
Infra-red spectrum	BP (Appendix II A)	Complies with authenticated reference material/IR spectrum
Assay		
Purity	BP (Appendix III A)	Not less than 98%

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
		<p>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 '<i><2232> Elemental Contaminants in Dietary Supplements</i>'. 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.</p>
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. 77 '<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 9 of the Order.</p>

Key to abbreviations:

BP = British Pharmacopoeia

CAS = Chemical Abstracts Services

USP = United States Pharmacopoeia