Compositional Guideline for Magnesium citrate – dibasic tetrahydrate

Name of the ingredient

Magnesium citrate – dibasic tetrahydrate (AAN)

Definition of the ingredient

Magnesium citrate – dibasic tetrahydrate has the molecular formula $C_6H_6MgO_7, xH_2O$, where $x = 4$.

Molecular mass: 286 (214.5 for anhydrous substance)

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White or almost white, fine hygroscopic powder
Characteristics		
Solubility	BP (General notice)	Soluble in water, dilute hydrochloric acid and dilute nitric acid; practically insoluble in ethanol (96%)
Appearance of solution	Ph Eur method 2.2.2, Method II (see Note 1)	The solution is not more intensely coloured than the reference solution BY6
pH of solution	Ph Eur method 2.2.3 (see Note 2)	3.5–4.5
Loss on drying (1.000 g dried in an oven for 5 h at	Ph Eur method 2.2.32	22.2–28.2%

Test	Method reference	Acceptance criteria
180±10°C		
Identification		
Citrate	Ph Eur method 2.3.1	Complies
Magnesium	Ph Eur method 2.3.1	Complies
Assay		
Magnesium	Ph Eur method 2.5.11	10.7–12.0% (dried basis)
Notes		
1. The test solution is prepared in the following manner: Dissolve 0.75g of the substance in 5 mL dilute hydrochloric acid R using heat. Cool and dilute to 30 mL with distilled water. 2. A 2.5% solution of the substance in carbon dioxide-free water.		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Heavy metals	Ph Eur method 2.4.8	No more than 10 ppm
Iron	Ph Eur method 2.4.9 (see Note 3)	No more than 100 ppm
Other organic or inorganic impurities or toxins		
Oxalates	As per Ph Eur monograph 2339	No more than 280 ppm
Sulfuric acid reaction (readily carbonisable substances)	Ph Eur method 2.2.2 (Method II) (see Note 4)	The solution is not more intensely coloured than the reference solution Y2
Sulfates	Ph Eur method 2.4.13 (see Notes 5)	No more than 0.2%

Test	Method reference	Acceptance criteria
Calcium	Ph Eur method 2.4.3 (see Note 6)	No more than 0.2%
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		
3. The solution used is prepared by diluting 4 mL of the test solution (see Note 1) to 10 mL with distilled water R. 4. Mix 0.2 g substance with 10 mL sulphuric acid R and heat in water bath at 90±1°C for 60 min. Cool rapidly. 5. The solution used is prepared by diluting 3 mL of the test solution (see Note 1) to 15 mL with distilled water R. 6. The solution used is prepared by taking 2 mL of the test solution (see Note 1) and 8 mL of distilled water R, and adding 0.2 mL of dilute ammonia solution R and adjusting the pH to 3.6 (according to Ph Eur method 2.2.3). Make up to a volume of 15 mL.		

Key to abbreviations: - insert or delete as required

BP = British Pharmacopoeia

Ph Eur = European Pharmacopoeia