



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional guideline for Trefriw Wells mineral water

Name of the ingredient

Trefriw Wells mineral water (AAN)

Definition of the ingredient

Trefriw Wells mineral water is a naturally-occurring mineral water containing Fe²⁺ (ferrous ion), sourced from Trefriw Wells Spa, North Wales, United Kingdom.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Clear, colourless liquid
Odour	Organoleptic	Slightly metallic
Characteristics		
pH	BP (Appendix V L)	2.5–3.5
Conductivity (at 20°C)	BP (Appendix V O)	1700–2500 µS/cm
Turbidity	BP (Appendix IV A)	No more than 2 FTU
Assay		
Ferrous ion (Fe ²⁺)	Colorimetric (FerroZine™)	166–219 mg/L

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Total heavy metals	AAS	Not more than 10 ppm
Chromium	AAS	Not more than 50 ppb
Selenium	AAS	Not more than 10 ppb
Cyanide	Colorimetric	Not more than 50 ppb
Beryllium	ICP-ES ¹	Not more than 60 ppb ¹
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues	Ph Eur method 2.8.13	Complies
Other organic or inorganic impurities or toxins		
Radiological quality		
Gross α activity	Evaporation or Coprecipitation method ¹	Not more than 0.5 Bq/L ¹
Gross β activity	Evaporation or Coprecipitation method ¹	Not more than 0.5 Bq/L ¹
Microbiology		
<i>Sporothrix</i> fungus	Culture ²	Absent in 100 mL
Iron-oxidising bacteria	Culture ²	Absent in 100 mL
<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>		

Test	Method reference	Acceptance criteria
Notes		
1.	NHMRC (2011), Australian Drinking Water Guidelines Paper 6 National Water Quality Management Strategy. http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/eh52_aust_drinking_water_guidelines_update_120710_0.pdf	
2.	Johnson DB and Hallberg KB (2007), Techniques for detecting and identifying acidophilic mineral-oxidising microorganisms. <i>Biomining</i> , Rawlings DE and Johnson DB (eds) pp 237-262. Hallberg KB and Johnson DB (2007), Isolation, enumeration, growth and preservation of acidophilic prokaryotes. In: <i>Manual of Environmental Microbiology</i> 3rd Edition. Hurst CJ, Crawford R, Garland JL, Lipson DA, Mills AL and Stetzenbach LD (eds). pp 1155-1165. American Society of Microbiology, Washington, DC. These references describe techniques for the detection of iron-oxidising bacteria, but they are also applicable to the detection of <i>Sporothrix</i> fungus.	

Key to abbreviations: -

AAS = Atomic absorption spectroscopy

BP = British Pharmacopoeia

Bq/L = Becquerel/L

FTU = Formazin turbidity unit

ICP-MS = Inductively coupled plasma emission spectroscopy

NHMRC = National Health and Medical Research Council

µS/cm = micro Siemens/cm