Compositional Guideline: *Rhodiola rosea* dried root (powdered) extract

Name of the ingredient

Rhodiola rosea L (AHN)

Definition of the ingredient

The ingredient is obtained by aqueous or hydroethanolic (with up to 70% ethanol v/v) extraction of the powdered dried root (rhizome) of *R. rosea* L only, and not from the root of any of the related species, such as *R. crenulata* (Hook. f. & Thomson) H. Ohba and *R. sacra* (Prain ex Raym.-Hamet) S.H. Fu. The typical native extraction ratio range is 6–10:1 for aqueous extraction and 3–5:1 for hydroethanolic extraction.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Brown, non-crystalline powder
Odour	Organoleptic	Rose-like
Characteristics		
Loss on drying	BP (Appendix IX D)	Not more than 5%
Identification		
Chemical fingerprint[1]	HPLC	Complies with authenticated reference material
Assay		

Test	Method reference	Acceptance criteria
Phenypropanoids[2]	HPLC	3.0–5.0%
Rosavin[3]	HPLC	1.5–3.5%
Salidroside[4]	HPLC	1.0–3.0%
Notes		
1. Test must be validated and capable of discriminating between *R. rosea* and related species especially *R. crenulata and R. sacra*. The suggested method is that by Ganzera *et al.* (2001) *Chemical and Pharmaceutical Bulletin* 49(4): 465-467. The HPLC profile should be compared against the 'fingerprint' of a genuine standard *R. rosea* extract, to not only confirm identity but also to determine if any additional peaks are those of potential contaminants. If the comparator 'fingerprint' is not available, the identity of peaks cannot be determined simply based on their retention time. In order to confirm the identity of each peak, peaks should be collected and specific characterisation performed (*e.g.* GC-MS, NMR or IR spectrum).		
2. The term "phenylpropanoids of *R. rosea*" comprises the sum of the compounds rosavin, rosarin and rosin. Rosin = 3-phenyl-2-propeny1-O-β-d-glucopyranoside Rosavin = 3-phenyl-2-propeny1-O-(6'-O-α-l-arabinopyranosyl)-β-d-glucopyranoside Rosarin = 3-phenyl-2-propeny1-O-(6'-O-α-l-arabinofuranosyl)-β-d-glucopyranoside.		
3. The term "rosavin" refers specifically to 3-phenyl-2-propeny1-O-(6'-O-α-l-arabinopyranosyl)-β-d-glucopyranoside. The test must be capable of discriminating this compound separately from other phenylpropanoids.		
4. A salidroside content in excess of the phenylpropanoid content is anomalous and may suggest that a preparation is not pure *R. rosea* extract.		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual solvents	BP (Appendix VIII L)	Complies
Incidental metals and non-metals		

Test	Method reference	Acceptance criteria
Heavy metals (as lead)	BP (Appendix VII)	Not more than 10 ppm
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues	BP (Appendix XI L)	Complies
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