# Compositional Guideline: Dried root (powdered) of *Rhodiola rosea*

## Name of the ingredient

Dried root (powdered) of *Rhodiola rosea* L (AHN)

## Definition of the ingredient

The ingredient is obtained for the dried, powdered root (rhizome) of *R. rosea* L (Crassulaceae) only. Care should be taken not to confuse this root with any of the related species, such as *R. crenulata* (Hook. f. & Thomson) H. Ohba and *R. sacra* (Prain ex Raym.-Hamet) S.H. Fu.

**Table 1. Ingredient specific requirements**

| Test | Method reference | Acceptance criteria |
|---|---|---|
| **Description** | | |
| Macroscopic – dried rootstock<br><br>Pieces of rootstocks and roots of different shapes. Rootstock pieces are hard and rugate with traces of died-off stalks and remnants of squamiform leaves. From the rootstocks a few roots branch off 2-9 cm long and 0.5-1 cm thick. Rootstock and root surface is glossy and of greyish-brown colour; on peeling off of cork there is a golden-yellow layer. Fracture colour is rosy-brown or light brown. | Visual | Complies |
| Microscopic – dried rootstock | Visual | Complies |

| Test | Method reference | Acceptance criteria |
|---|---|---|
| On the rootstock cross cut is seen a schistous periderm. Rootstock structure is of fascicular type. Duct fascicles are open, collateral, fusiform, ring-shaped, rootstock periphery-oriented by phloem and centre-oriented by xylem. There may be available the second ring of smaller duct fascicles, in which phloem is centre-oriented, while xylem is periphery-oriented. Rootstock parenchyma consists of large cells filled by starch. Starch grains are simple, round or oval, 5-20 µm in diameter | | |
| Odour | Organoleptic | Rose-like |
| **Characteristics** | | |
| Loss on drying | BP (Appendix IX D) | Not more than 12% |
| **Identification** | | |
| Chemical fingerprint[1] | HPLC | Complies with authenticated reference material |
| **Assay** | | |
| Phenylpropanoids[2] | HPLC | Not less than 1.8% |
| Rosavin[3] | HPLC | Not less than 1.2% |
| Salidroside[4] | HPLC | Not less than 0.6% |
| **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.* | | |

| Test | Method reference | Acceptance criteria |
|---|---|---|
| *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.<br><br>Rosin = 3-phenyl-2-propeny1-O-β-d-glucopyranoside<br>Rosavin = 3-phenyl-2-propeny1-O-(6'-O-α-l-arabinopyranosyl)-β-d-glucopyranoside<br>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* powder. | | |

**Table 2. Incidental constituents**

| Test | Method reference | Acceptance criteria |
|---|---|---|
| **Incidental metals and non-metals** | | |
| 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 |
| **Other organic or inorganic impurities or toxins** | | |
| Ash | BP (Appendix XI J) | Not more than 8% |
| **Microbiology** | | |
| While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is | | |

| Test | Method reference | Acceptance criteria |
|---|---|---|
| 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