



CHIEF PHARMACEUTICAL INSPECTOR

IWSF.405.47.2022.IP.2
WTC/0074_01_02/75

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC as amended

Chief Pharmaceutical Inspector*/the Competent Authority of Poland/*

confirms the following:

the manufacturer

Zakład Zielarski „KAWON - HURT” Nowak Spółka Jawna
Krajewice 119, 63-800 Gostyń, POLAND

site address

Zakład Zielarski „KAWON - HURT” Nowak Spółka Jawna
Krajewice 119, 63-800 Gostyń, POLAND

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2021, item 1977 as amended) in connection with registration no **31/WTC0074/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **01-03/02/2022**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, Directive 91/412/EEC and the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

Elder flower, Hawthorn leaf and flower, Calendula flower, Meadowsweet flower, Sandy everlasting, Lime flower, Green bean pod, Iceland moss, Corn silk, Blessed thistle herb, St. John's wort, Wild pansy (flowering aerial parts), Yarrow, Wild thyme, Melilot, Goldenrod; European, Wormwood, Knotgrass, Motherwort, Equisetum stem, Eyebright, Thyme, Centaury, Birch leaf, Ribwort plantain, Bogbean leaf, Blackberry leaf, Melissa leaf, Peppermint leaf, Walnut leaf, Tussilago leaf, Nettle leaf, Senna leaf, Sage leaf, Fenugreek, Angelica archangelica root, Chicory root, Valerian root; cut, Lovage root, Liquorice root, Burdock root, Dandelion root, Marshmallow root, Tormentil, Couch grass rhizome, Rhubarb, Restharrow root, Oak bark, Frangula bark, Willow bark, Sage leaf, Wild pansy (flowering aerial parts), Sedative herbs, Laxative herbs, Diuretic herbs.

3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps (drying, milling, sieving)</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

Arnica flower, Mullein flower, Matricaria flower, Lavender flower, Hop strobile, Lingonberry leaf, Bearberry leaf, Rosemary leaf, Aniseed, Bilberry fruit; dried, Caraway fruit, Coriander, Juniper, Fennel bitter, Linseed.

3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying, sieving) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Any restrictions or clarifying remarks related to the scope of this certificate:

The certificate was issued on the basis of a remote inspection.



Chief Pharmaceutical Inspector

Krajewska

Ewa Krajewska