

Subject: Technical Data Sheet

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Authorised By: Steve Hurt

Effective date: 11/09/2020

PRODUCT NAME: PELAPOWERTM 1100

BOTANICAL NAME: PELARGONIUM SIDOIDES

FAMILY: GERANIACEAE

PRODUCT CODE: FPPSPEX1100



PRODUCT DESCRIPTION

Vacuum dried Pelargonium sidoides root powdered extract, standardised to 1100ppm Umckalin.

EXTRACTION SOLVENT

Hydro-ethanolic extraction. Ethanol 60% (m/m) Produced from Ethanol 96% (Ph. Eur) and water for preparation of extracts (Ph. Eur).

COMPOSITION OF FORMULATED INGREDIENTS

Pelargonium sidoides root powdered extract blended with maltodextrin or microcrystalline cellulose (MCC).

RATIO OF HERBAL DRUG TO DRUG PREPARATION (= NATIVE EXTRACT)

4 – 25: 1

GEOGRAPHICAL ORIGIN OF THE PLANT

Occurs throughout Lesotho and the Eastern Cape and Free State of the Republic of South Africa.

Produced in South Africa.

PLANT PART USED

Tuber(root) of the Pelargonium Sidoides plant.

ANALYTICAL DATA

PARAMETER	TEST METHOD	SPECIFICATION	UNIT OF MEASURE
Appearance	Visual / sensory WHO/Pharm/92.599/rev 1 page 10	Reddish brown to brown powder	-
Identification as per TLC	TLC	The Rf bands of the sample corresponds to the Rf bands of the reference sample.	-
Solubility	Ph. Eur.	1 % soluble in water without sediment	-
Moisture	Ph. Eur. 2.2.32 / Ph. Eur 1.8.17	≤ 10.0	% (m/m)
Bulk density	Ph. Eur. 2.9.34	Batch specific determination	g /ml
Residual solvent ethanol	WIN-VM-719 (GC)	< 0.5	% (m/m)
Assay – Umckalin	WIN-VM-588 (HPLC)	>/= 1100 ppm	ppm
Content of Umckalin and Umckalin-7- sulphate calculated as Scopoletin	WIN-VM-588 (HPLC)	Batch Specific determination (Range 500 – 3600)	ppm
Total Phenols	Folin Ciocalteu Method	Batch Specific determination	% (m/m)
Total Tannins	Pyrogallol as reference as per Ph. Eur. Method 2.8.14 (WIN-VM-593)	> 2	% (m/m)

HEAVY METALS

PARAMETER	TEST METHOD	SPECIFICATION	UNIT OF MEASURE
Lead (Pb)	WIN-VM-085 (ICP-MS)	< 5	ppm
Cadmium (Cd)	WIN-VM-085 (ICP-MS)	< 0.5	ppm
Arsenic (As)	WIN-VM-085 (ICP-MS)	< 1	ppm
Mercury (Hg)	WIN-VM-085 (ICP-MS)	< 1	ppm


**Test method used to determine heavy metals: WIN-VM-049*

MICROBIOLOGICAL CHARACTERISTICS

PARAMETER	TEST METHOD	SPECIFICATION	UNIT OF MEASURE
Total Microbial Activity (TMA) SWJM 35 (Ph. Eur 2.4.27	< 10 000	CFU/g
Salmonella SWJM 67	Ph. Eur 2.4.27	< 10 *	Per 25g
Coliforms SWJM 48	Ph. Eur 2.4.27	< 10 *	CFU/g
Escherichia coli SWJM 62	Ph. Eur 2.4.27	< 100 *	CFU/g
Yeast SWJM 50	Ph. Eur 2.4.27	< 500	CFU/g
Mould SWJM 50	Ph. Eur 2.4.27	< 500	CFU/g


*For where the test result is < 10, it means that no colonies/microbial growth ("No growth") was observed at the lowest/ first dilution (1 in 10 dilution) of the sample. CFU = Colony-Forming Unit (A colony-forming unit is a unit used to estimate the number of viable bacteria or fungal cells in a sample. Viable is defined as the ability to multiply via binary fission under the controlled conditions.)

SHELF LIFE

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36 Months.												
PACKAGING												
<p>1 kg: Foil zip lock bag made from MET PET/LLDPE (110 microns). 15 kg: Double 50 micron food grade plastic bags in a bucket with a lid.</p> <table border="0" data-bbox="178 701 1353 947"> <tr> <td>PRODUCT:</td> <td>Pelargonium extract</td> </tr> <tr> <td>NET MASS:</td> <td>15 kg</td> </tr> <tr> <td>GROSS MASS:</td> <td>16 kg</td> </tr> <tr> <td>PRIMARY PACKAGING:</td> <td>640mm (open end) x 670mm Metalised Pet Barrier with 50mic Inner Liner Open Top Bag</td> </tr> <tr> <td>SEAL:</td> <td>Heat sealed</td> </tr> <tr> <td>BUCKET:</td> <td>25lt AlphaPac Pail</td> </tr> </table>	PRODUCT:	Pelargonium extract	NET MASS:	15 kg	GROSS MASS:	16 kg	PRIMARY PACKAGING:	640mm (open end) x 670mm Metalised Pet Barrier with 50mic Inner Liner Open Top Bag	SEAL:	Heat sealed	BUCKET:	25lt AlphaPac Pail
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TRANSPORTATION												
Enclosed vehicle, which is clean, dry, pest and chemical free. Vehicle should be suitable for the transportation of foodstuffs. Vehicle not to present any physical hazards e.g. glass and hard plastics.												
STORAGE CONDITIONS												
Stored at ambient temperatures, labelled, sealed, protected from moisture, light and high temperatures in a pest and rodent-proof area, away from harmful chemicals.												
PREPARATION AND/OR HANDLING BEFORE USE OR PROCESSING												
Use as is.												

FOOD SAFETY RELATED ACCEPTANCE CRITERIA OR SPECIFICATIONS OF PURCHASED MATERIALS AND INGREDIENTS APPROPRIATE FOR THEIR INTENDED USE
To be used as an ingredient in the preparation of herbal medicine or food supplements.
STATUTORY AND REGULATORY FOOD SAFETY REQUIREMENTS
No additional requirements.
POTENTIAL ABUSE OF PRODUCT
Storing in direct sunlight, unprotected from moisture and high temperatures. Not tightly closing after opening.

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ALLERGEN STATEMENT
<p>The above-mentioned product is made of allergen-free ingredients. This product does not contain allergens subject to labelling according to regulation (EU) No. 1169/2011 and amendments. Process controls are in place to ensure that no accidental contamination with allergenic material could occur.</p>
GMO STATEMENT
<p>This product has not been in contact with any GMO, therefore the regulations (EC) 1829/2003 and (EC) 1830/2003 are not applicable.</p>
TSE/BSE STATEMENT
<p>In the production process of this product, we do not use any raw material of animal origin. This product has not been in contact with and does not include any material of animal origin. Our product is not contaminated with material of animal origin when it leaves our storage facility.</p>
KOSHER/HALAL STATUS
<p>Not Certified.</p>

Disclaimer - This product specification describes the composition and properties of our product to the best of our knowledge. Due to raw material variations deviations from this specification may occur within good manufacturing practice in order to standardize our product. This product and its ingredients conform to the South African food law requirements. The permissibility of our product may be limited to certain applications. It's the duty of the user to insure that the use of our product and the placing on the market of the pharmaceutical or cosmetic product made with it complies with local applicable legal requirements.