


PRODUCT SPECIFICATION SHEET

PRODUCT NAME:	PELAPOWER™ 1100
PRODUCT CODE:	FPPSPEX1100MAS
BOTANICAL NAME:	PELARGONIUM SIDOIDES
HS CODE:	1211.90.9195
	
PRODUCT DESCRIPTION:	Vacuum dried <i>Pelargonium sidoides</i> 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).
DRUG : EXTRACT RATIO NATIVE (DERn):	4 – 25 : 1
COMPOSITION OF FORMULATED INGREDIENTS:	Pelargonium sidoides root powdered extract blended with maltodextrin.
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:	Radix. Tuber(root) of the Pelargonium Sidoides plant.
CHARACTERISTIC:	Reddish brown to brown powder, herbal taste and aroma with astringent notes.

ANALYTICAL DATA

PARAMETER	METHOD	SPECIFICATION	UNIT OF MEASURE
APPEARANCE:	Visual/sensory	Reddish brown to brown powder	-
IDENTIFICATION:	TLC	The Rf bands of the sample corresponds to the Rf bands of the reference sample.	-
MOISTURE:	Ph. Eur. 2.2.32 / Ph. Eur 1.8.17	< 10	% (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)
SOLUBILITY:	Ph. Eur.	Sparingly soluble in water and ethanolic solutions.	

ASSAY – UMCKALIN:	HPLC	>/= 1100 ppm	ppm
CONTENT OF UMCKALIN AND UMCKALIN-7-SULPHATE CALCULATED AS SCOPOLETIN:	HPLC	Batch specific determination	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)	> = 2.0	% (m/m)

MICROBIAL SPECIFICATION

TOTAL PLATE COUNT (TPC):	SWJM 35	< 10 000	CFU/g
SALMONELLA*:	SWJM 67	< 10	Per 25g
COLIFORMS*:	SWJM 48	< 10	CFU/g
ESCHERICHIA COLI*:	SWJM 62	< 10	CFU/g
YEAST:	SWJM 50	< 500	CFU/g
MOULD:	SWJM 50	< 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.)*

HEAVY METALS

LEAD:	WIN-VM-049	< 5	mg/kg
CADMIUM:	WIN-VM-049	< 0.5	mg/kg
MERCURY:	WIN-VM-049	< 1	mg/kg
ARSENIC:	WIN-VM-049	< 1	mg/kg

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

SHELF LIFE

36 Months

PACKAGING

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.

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

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.

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Authorised By: Steve Hurt		Effective date: 09/12/2020	
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.			
ALLERGEN STATEMENT			
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.			
GMO STATEMENT			
This product has not been in contact with any GMO, therefore the regulations (EC) 1829/2003 and (EC) 1830/2003 are not applicable.			
TSE/BSE STATEMENT			
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.			
KOSHER/HALAAL STATUS			
HALAAL certified.			

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.



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