



herbatica

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## CERTIFICATE OF ANALYSIS

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<b>Product Name</b>	<b>Ashwagandha Extract</b>
<b>Product Code</b>	<b>0130</b>
<b>Batch No.</b>	<b>C231667</b>
<b>TR No.</b>	<b>KL23F0716</b>
<b>Date of Manufacture</b>	<b>October 2023</b>
<b>Date of Expiry</b>	<b>September 2028</b>

Category	Intended for Nutraceutical application
Botanical/Scientific name	Withania somnifera
CAS No	90147-43-6
Plant part	Roots
Preparation type	Extraction
Solvent used for extraction	Ethanol
Solvent used in manufacture	None
Final extract ratio	5:1 to 8: 1
Standardization	Alkaloids, Withanolides, Withaferin-A
Excipient used	Maltodextrin

	<b>Excipient name</b>	<b>%Used</b>	<b>CAS No.</b>
	Maltodextrin	25% to 50%	9050-36-6
<b>Parameters</b>	<b>Result</b>	<b>Limit</b>	<b>Reference</b>
<b>PHYSICAL</b>			
Description	Complies	Brown to dark brown powder with characteristic odour	Visual and Organoleptic
Identification	Complies	To comply by TLC for a) Alkaloids and b) Withanolides	SLL/STP-A-012
Solubility			SLL/STP-S-028
-Water solubles (1% w/v solution in water)	90.63 % w/w	Not less than 70.0% w/w	

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**Product Name** Ashwagandha Extract  
**Product Code** 0130  
**Batch No.** C231667  
**TR No.** KL23F0716  
**Date of Manufacture** October 2023  
**Date of Expiry** September 2028

<b>Parameters</b>	<b>Result</b>	<b>Limit</b>	<b>Reference</b>
-Alcohol solubles (1% w/v solution in 50% v/v alcohol)	77.99 % w/w	Not less than 60.0% w/w	
Loss on drying	4.34 % w/w	Not more than 5.0% w/w (dried at 105°C)	EP 2.2.32
Ash content	2.17 % w/w	Not more than 15.0% w/w	EP 2.4.16 Method - II
Tapped bulk density	0.83 g/ml	Between 0.60g/ml and 0.85g/ml	EP 2.9.34 Method - I
Loose bulk density	0.50 g/ml	Record	EP 2.9.34 Method - I
Sieve Test (Passes through)			USP <786>
- 20 mesh	100.00 % w/w	Not less than 100% w/w	
- 40 mesh	100.00 % w/w	Not less than 85% w/w	
- 80 mesh	96.08 % w/w	Not less than 70% w/w	
<b>CHEMICAL</b>			
Assay			
-Content of Alkaloids by Gravimetry	1.17 % w/w	Not less than 1.0% w/w	SLL/STP-A-051
-Content of total Withanolides (free Withanolides and Glycowithanolides) by Gravimetry	7.20 % w/w	Not less than 7.0% w/w and not more than 10.0% w/w	SLL/STP-W-005
-Content of Withaferin-A by HPLC	0.20 % w/w	Not more than 2.0% w/w	SLL/STP-W-004
<b>OTHERS</b>			

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<b>Parameters</b>	<b>Result</b>	<b>Limit</b>	<b>Reference</b>
Lead	<0.2 ppm (µg/g)	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	<0.2 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	<0.2 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Mercury	<0.02 ppm (µg/g)	Not more than 0.1ppm (µg/g)	USP <2232>
Residual solvents	Complies	To comply as per EU Directive 2009/32/EC	USP <467>
Residual pesticides	Complies	To comply as per EP	USP <561>
Poly Aromatic Hydrocarbons (PAH)			SLL/STP-P-109
-Benzo(a)pyrene	Complies	Not more than 10ppb (µg/kg)	
-PAH4 (Sum of Benzo(a)pyrene, Benz(a)anthracene, Benzo(b)fluoranthene and Chrysene)	Complies	Not more than 50ppb (µg/kg)	
Ethylene oxide (Sum of Ethylene oxide and 2-Chloroethanol)	Complies	Not more than 100ppb (µg/kg)	SLL/STP-E-015
<b>MICROBIOLOGICAL PROFILE</b>			
Total aerobic microbial count	1000 cfu/g	Not more than 5000cfu/g	EP 2.6.31
Total yeasts and molds count	10 cfu/g	Not more than 100cfu/g	EP 2.6.31
Escherichia coli	Complies	Negative/10g	EP 2.6.31

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<b>Parameters</b>	<b>Result</b>	<b>Limit</b>	<b>Reference</b>
Salmonella	Complies	Negative/25g	EP 2.6.31
Staphylococcus aureus	Complies	Negative/10g	EP 2.6.13
Pseudomonas aeruginosa	Complies	Negative/10g	EP 2.6.13
Bile tolerant Gram negative bacteria	<10 cfu/g	Not more than 100cfu/g	EP 2.6.31
Coliforms	<10 cfu/g	Less than 10cfu/g	BAM Chapter 4

### **ADDITIONAL INFORMATION**

Nature	Hygroscopic
Sanitising treatment	Non-irradiated and not treated with ETO
Certification Status (Kosher/Halal)	Kosher and Halal certified
BSE/TSE status	BSE / TSE free
Genetic Modification Status	GMO free
Country of Origin	India
Cultivated or wild crafted	Cultivated
Storage condition	Store at room temperature in a air tight container. Avoid exposure to moisture.
Manufactured By	Sami-Sabinsa Group Limited - Peenya 19/1, 19/2, I Main II Phase, Peenya Industrial Area, Bangalore. 560 058, Karnataka, India
Manufactured At	Sami-Sabinsa Group Limited - Kunigal Plot No. 30-35, KIADB Industrial Area, Kunigal, Tumkur District - 572130

Vystavil: Andrej Valentovič , ALTEVITA s.r.o.,  
Dňa : 5.6..2024

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