



Sabinsa Poland Sp. z o.o.

*Pharmaceuticals *Phytochemicals
*Fine Chemicals *Herbal Extracts
*Cosmeceuticals *Specialty Chemicals

CERTIFICATE OF ANALYSIS

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Product Name Ashwagandha Extract
Product Code 0130
Batch No. H211491
TR No. HY21F0620
Date of Manufacture November 2021
Date of Expiry October 2026

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

Excipient name	%Used	CAS No.
Maltodextrin	25% to 50%	9050-36-6

Parameters	Result	Limit	Reference
PHYSICAL			
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)	87.08 % w/w	Not less than 70.0% w/w	
-Alcohol solubles (1% w/v solution in 50% v/v alcohol)	76.31 % w/w	Not less than 60.0% w/w	
Loss on drying	1.96 % w/w	Not more than 5.0% w/w (dried at 105°C)	EP 2.2.32
Ash content	4.20 % w/w	Not more than 15.0% w/w	EP 2.4.16 Method - II
Tapped bulk density	0.74 g/ml	Between 0.60g/ml and 0.85g/ml	EP 2.9.34 Method - I

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Parameters	Result	Limit	Reference
Loose bulk density	0.49 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	97.63 % w/w	Not less than 85% w/w	
- 80 mesh	73.38 % w/w	Not less than 70% w/w	
CHEMICAL			
Assay			
-Content of Alkaloids by Gravimetry	1.03 % w/w	Not less than 1.0% w/w	SLL/STP-A-051
-Content of total Withanolides (free Withanolides and Glycowithanolides) by Gravimetry	9.07 % 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	0.32 % w/w	Not more than 2.0% w/w	SLL/STP-W-004
OTHERS			
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

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Product Name Ashwagandha Extract
Product Code 0130
Batch No. H211491
TR No. HY21F0620
Date of Manufacture November 2021
Date of Expiry October 2026

Parameters	Result	Limit	Reference
-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)	
MICROBIOLOGICAL PROFILE			
Total aerobic microbial count	<100 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
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 2001, 8th Edition, 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.

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Product Name	Ashwagandha Extract
Product Code	0130
Batch No.	H211491
TR No.	HY21F0620
Date of Manufacture	November 2021
Date of Expiry	October 2026

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 - Hyderabad
Plot No.12A,Alexandria Knowledge Park, Genome Valley, Turkapally,Shameerpet - Mandal, R.R. District-500 078,Telangana,INDIA

Remarks

*Since it is a herbal product, there is likely to be minor colour variation from batch to batch of the product because of the geographical and seasonal variations of the raw material.
*Natural products can be hygroscopic and may agglomerate sometimes. It is suggested to sift the product before use.

The above certificate of analysis is based on **Specifications Issue No: 6 Dated: August 26, 2021**

NAP:Not Applicable

NAV:Not Available

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