



Sabinsa Poland Sp. z o.o.

*Pharmaceuticals *Phytochemicals

*Fine Chemicals *Herbal Extracts

*Cosmeceuticals *Specialty Chemicals

CERTIFICATE OF ANALYSIS

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Product Name	Rebersa® Chloride (Berberis Aristata Extract) EU
Product Code	0205EU
Batch No.	H211694
TR No.	HY21F0697
Date of Manufacture	December 2021
Date of Expiry	November 2026

Category Intended for Nutraceutical and Cosmeceutical application

Botanical/Scientific name Berberis aristata

CAS No 89957-84-6

Plant part Roots

Preparation type Extraction

Solvent used for extraction Ethanol

Solvent used in manufacture None

Final extract ratio 40:1

Standardization Berberine chloride

Parameters	Result	Limit	Reference
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PHYSICAL

Description	Complies	Yellow crystalline powder, almost odourless, taste very bitter*	Visual and Organoleptic
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Identification	Complies	To comply by HPLC	SLL/STP-B-028
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Solubility	Complies	Freely soluble in hot water	USP
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Water content by KF method	12.93 % w/w	Not more than 16.5% w/w	USP <921>
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Ash content	0.06 % w/w	Not more than 1.0% w/w	EP 2.4.16 Method - II
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Clarity of solution	Complies	A 0.2% w/v solution in water is clear	Visual
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Parameters	Result	Limit	Reference
Acidity	Complies	Consumes not more than 0.1ml of 0.1N sodium hydroxide for neutralizing 1% w/v solution in water	USP <401>
Tapped bulk density	0.42 g/ml	Between 0.40g/ml and 0.70g/ml	EP 2.9.34 Method - I
Loose bulk density	0.24 g/ml	Between 0.15g/ml and 0.35g/ml	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	85.12 % w/w	Not less than 80% w/w	
- 80 mesh	54.61 % w/w	Not less than 25% w/w	
CHEMICAL			
Assay			
-Content of Berberine chloride by HPLC	100.09 % w/w	Not less than 97.0% w/w and not more than 102.0% w/w on anhydrous basis	SLL/STP-B-028
OTHERS			
Lead	<0.20 ppm (µg/g)	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	<0.20 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	<0.20 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>

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Parameters	Result	Limit	Reference
Residual solvents	Complies	To comply as per EU Directive 2009/32/EC	USP <467>
Residual pesticides	Not applicable	Not applicable	
Poly Aromatic Hydrocarbons (PAH)			SLL/STP-P-078
-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 2.6.12
Total yeasts and molds count	<10 cfu/g	Not more than 100cfu/g	EP 2.6.12
Escherichia coli	Complies	Negative/10g	EP 2.6.13
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	Complies	Negative/10g	EP 2.6.13
Coliforms	<10 cfu/g	Less than 10cfu/g	BAM 2001, 8th Edition, Chapter 4
ADDITIONAL INFORMATION			
Sanitising treatment	Non-irradiated and not treated with ETO		

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Certification Status (Kosher/Halal)	Kosher certified, Halal certified
Genetic Modification Status	GMO free
BSE/TSE status	BSE / TSE free
Cultivated or wild crafted	Wild crafted
Country of Origin	India
Storage condition	Store at room temperature
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 **Specifications Issue No: 3 Dated: February 18, 2019** on

****In-House developed and validated methods**

NAP:Not Applicable

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NAV:Not Available

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