

Certificate of Analysis: BERBERINE

ANALYSIS REPORT VZ-19020021-1

Submitter code : 101605

Order number :

Quote :

Bruz, le 12/02/2019

SAMPLE NUMBER : 19020021

Received on : 01/02/2019

Name : Berberine (BR500A)

Brand :

Batch : D12320

Identifying Supplier :

Manufacturing date :

Ref. of the formula/raw material:

Best before end : 00/09/2020

Storage conditions : Room temperature

Packaging : Plastic pillbox

MICROBIOLOGICAL RESULTS

Analyses(Methods)	Results	Reference values	Unit
Microbiology ^{STA}	Voir fichier joint / See attached file		

Comments :

C.LE ROUX
Technical and Development Manager



COMPTE-RENDU D'ANALYSES MICROBIOLOGIQUES

Germes recherchés (Méthodes)	Critères (m)	Résultats
Bactéries gram-négatives résistantes aux sels biliaires / g (Pharmacopée européenne 9.0)	100	< 100
Escherichia coli / g (Pharmacopée européenne 9.0)	Absence	Absence
Germes aérobies viables totaux / g (Pharmacopée européenne 9.0)	10 000	< 100
Levures et moisissures totales / g (Pharmacopée européenne 9.0)	100	< 10
Salmonella / 25 g (Pharmacopée européenne 9.0)	Absence	Absence

m = critère Règlement CE 2073/2005 ou critère revue de contrat si précisé.

Conclusion :

Au vu des critères mentionnés, la qualité microbiologique est : **SATISFAISANTE**

Pour déclarer, ou non, la conformité à la spécification, il n'a pas été tenu explicitement compte de l'incertitude associée au résultat. L'évaluation de cette incertitude de mesure est disponible sur simple demande.

Validé le **11 février 2019**

Laurent THOMAS
Responsable Technique





Berberis Roots HA PE 97% Berberine HPLC

Product Code :

1504170

Certificate of Analysis

Version SDS	Date	Conclusion	Written by	Sign
003	2018-05-23	Conform	C.ROINOX Quality Insurance	
			Validated by	Sign
			M.LEVESQUE Quality manager	

Manufacturing **

Botanical Name	<i>Berberis vulgaris</i>		
Part used	Roots		
Approx. Ratio Plant : Extract	Up to assay		
Extraction solvent	Ethanol / Water		
Additives / Carrier	None		
Batch number	O-1504170-180422	Manufacture Date	2018-04
		Best Before Date	2020-04

Properties	Specifications	Results **
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Organoleptic **

Appearance	Yellow powder	Complies
Odor & taste	Characteristic	Complies

Physical and Chemical **

Loss on drying	≤ 15%	2.50%
Total ashes	≤ 10%	0.39%
Bulk density	ND	-
Particle size	≥ 90% pass through #80 mesh	Complies

Assay **

Berberine hydrochloride	≥ 97.0% by HPLC, internal method	97.35%
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Microbiological * / **

Total Plate Count	≤ 10 000 CFU/g ***	10 CFU/g
Yeast and Mould	≤ 100 CFU/g ***	10 CFU/g
<i>Escherichia coli</i>	Negative	Complies
<i>Salmonella</i> spp	Negative	Complies

Contaminants * / **

Cadmium	≤ 1 ppm	0.0342 ppm
Lead	≤ 3 ppm	0.1302 ppm
Mercury	≤ 0.1 ppm	0.0930 ppm
Arsenic	≤ 1 ppm	0.1262 ppm

Shelf Life

Shelf Life	Min 2 years	
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Allergens **

Allergens **	Certified in compliance with Regulation 1169/2011/EC	
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Ionisation **

Ionisation **	Certified in compliance with Regulation 1999/2/CE & 1999/3/EC.	
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TSE/BSE **

TSE/BSE **	Certified in compliance with Regulation 999/2001/EC	
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Nanomaterials **

Nanomaterials **	Certified in compliance with Decree 2012/232 & Decree dated August 6th, 2012	
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GMO **

GMO **	Certified in compliance with Regulation 1829/2003/EC & 1830/2003/EC	
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*According to a control plan

**Based on our producer's information

***Acceptable maximal count: 5 times the acceptance criterion according to European Pharmacopoeia VIII° Edition 5.1.8 Category B

Remarks :

-To be stored in original tightly closed package away from moisture and sunlight

-Since it is an herbal product, there is likely to be minor colour variation from batch to batch because of the seasonal variations of raw materials. Colour change will not affect the quality and efficacy of the product.

Abbreviations: ND: not determined / NA: not applicable / HA : Hydroalcoholic / PE: Powder extract / FE : Fluid extract / SE : Soft extract