

CERTIFICATE OF ANALYSIS

Name: 0373-803 - Ballotae nigrae herb.T norm.1L

Werkorder: 146414

Lot number: 20E19/V12316

Expiry date: 30/04/2023

Parameter	Measured Value	Specification Value Range	Analysis Method
Reference			
REFERENCE: Conforma			
Characters			
Description: Dark brown liquid	conform	conform	
Identification			
HPTLC	positive	positive	Conforma
Tests			
Relative density	0,926	0,920 - 0,940	Ph. Eur.
Ethanol	56,9 % V/V	> 55,0 % V/V	Conforma
Methanol	< 0,05 % V/V	< 0,05 % V/V	Conforma
2-Propanol	< 0,05 % V/V	< 0,05 % V/V	Conforma
Ratio herb/native extract	1/6		Ph. Eur.
Microbial contamination			
TAMC	50 cfu/g	< 10.000 cfu/g	Ph. Eur.
TYMC	0 cfu/g	< 100 cfu/g	Ph. Eur.
Bile-tolerant gram-negative bacteria	0 cfu/g	< 100 cfu/g	Ph. Eur.
E. coli	absent in 1g	absent in 1g	Ph. Eur.
Salmonella	absent in 25g	absent in 25g	Ph. Eur.
Assay			
Total ortho-dihydroxycinnamic acid derivatives: expressed as acteoside	0,5 % m/m	0,4 - 0,6 % m/m	Conforma
Release			
Conclusion	conform	conform	
Date	03/02/2021		

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Signed by: Filip Van Houtte
Qualified Person