

CERTIFICATE OF ANALYSIS

Name: 0374-553 - Ballotae nigr.herb.EF norm250g

Werkorder: 152392

Lot number: 21J21/V19462

Expiry date: 30/09/2024

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	1,04	1,00 - 1,10	Ph. Eur.
Ethanol	23,4 % V/V	> 22,0 % 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	3/4		Ph. Eur.
Microbial contamination			
TAMC	70 cfu/g	< 100.000 cfu/g	Ph. Eur.
TYMC	< 10 cfu/g	< 10.000 cfu/g	Ph. Eur.
Bile-tolerant gram-negative bacteria	0 cfu/g	< 10.000 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	2,0 % m/m	1,5 - 2,0 % m/m	Ph. Eur.
Release			
Conclusion	conform	conform	
Date	24/02/2022		

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Signed by: Filip Van Houtte
Qualified Person