

CERTIFICATE OF ANALYSIS

Name: 0014-043 - Opii T normata PhEur. 100g

Werkorder: 146088

Lot number: 21A18/V13851

Expiry date: 31/12/2023

Parameter	Measured Value	Specification Value Range	Analysis Method
Reference			
REFERENCE: Ph. Eur.			
Characters			
Manufacturing date	27/01/2021		
Description: Reddish-brown liquid	conform	conform	Ph. Eur.
Identification			
Thin-layer chromatography	positive	positive	Ph. Eur.
Tests			
Residue on drying	6,7 % m/m	> 4,0 % m/m	Ph. Eur.
Ethanol content	33 % V/V	31 - 34 % V/V	Conforma
Thebaine	0,2 % m/m	< 0,3 % m/m	Ph. Eur.
Ratio herb/native extract	1/9		Ph. Eur.
Microbial contamination			
TAMC	< 10 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			
Morphine	1,00 % m/m	0,95 - 1,05 % m/m	Ph. Eur.
Codeine	0,3 % m/m	> 0,1 % m/m	Ph. Eur.
Release			
Conclusion	conform	conform	
Date	22/04/2021		

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Signed by: Filip Van Houtte
Qualified Person

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