

CERTIFICATE OF ANALYSIS

Name: 0145-359 - Belladonnae fo.ES norm.PH 25g

Werkorder: 153509

Lot number: 20H04/V17406

Expiry date: 31/07/2023

Parameter	Measured Value	Specification Value Range	Analysis Method
Reference			
REFERENCE: Ph. Eur.			
Sampling			
Original Manufacturer: Gehrlicher Pharmaceutical Extracts GmbH	conform	conform	
Supplier (Distributor): Gehrlicher Pharmaceutical Extracts GmbH	conform	conform	
Characters			
Description: Brown or greenish, hygroscopic powder	conform	conform	
Identification			
A.: Thin-layer chromatography	positive	positive	Ph. Eur.
B.: Thin-layer chromatography for atropine	positive	positive	Ph. Eur.
Tests			
Loss on drying	3,4 % m/m	< 5,0 % m/m	Ph. Eur.
Atropine	conform	conform	Ph. Eur.
Ratio herb/native extract	7/1		Ph. Eur.
Microbial contamination			
TAMC	25 cfu/g	< 100.000 cfu/g	Ph. Eur.
TYMC	0 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 alkaloids: expressed as hyoscyamine (dried extract)	1,00 % m/m	0,95 - 1,05 % m/m	Ph. Eur.
Additional information			
Lactosum monohydricum	18 %		Ph. Eur.
Release			
Conclusion	conform	conform	
Date	06/12/2021		

This is a computerised print of the original, signed report of analysis.

This report of analysis is valid without any subscription.

Signed by: Filip Van Houtte

Qualified Person