

# CERTIFICATE OF ANALYSIS

Name: 0457-275 - Tolutani balsami sirupus 1L

Werkorder: 127165

Lot number: 19E21/V00563

Expiry date: 30/04/2022

Parameter	Measured Value	Specification Value Range	Analysis Method
<b>Reference</b>			
REFERENCE: Conforma			
<b>Characters</b>			
Description: Clear, gold-yellow, viscous liquid	conform	conform	
<b>Identification</b>			
A.: Tolu balsam, methylparaben, propylparaben : HPTLC	positive	positive	Conforma
B.: Saccharose : HPTLC	positive	positive	Conforma
C.: Propylene glycol : HPTLC	positive	positive	Conforma
<b>Tests</b>			
Relative density	1,312	1,300 - 1,320	Ph. Eur.
Refractive index	1,455	1,450 - 1,460	Ph. Eur.
<b>Microbial contamination</b>			
TAMC	0 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.
<b>Assay</b>			
Methylparaben	0,079 % m/m	0,072 - 0,088 % m/m	Conforma
Propylparaben	0,019 % m/m	0,018 - 0,022 % m/m	Conforma
Balsamic acid: as cinnamic acid	0,10 % m/m	0,10 - 0,11 % m/m	Conforma
<b>Release</b>			
Conclusion	conform	conform	
Date	17/06/2019		

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Signed by: Marta Donadoni  
Qualified Person