

## Certificate of Analysis

**Productname:** Sirupus simplex  
**Number of analysis/Inspection Code:** 1 / KEUR-180701B  
**Batchnumber:** 20B19-F08  
**Reference code / No.:** 1093 / 20A14/V05168  
**Analysed according to:** INTERN

Tests	Requirement	Result	Unit	Standard remark
Appearance	Clear, almost colourless, sirupy liquid	Conform		Data producer
Refractive index	1,440 - 1,456	1,447		Data producer
Relative density	1,285 - 1,320	1,308		Data producer
Identification Sucrose	Conform	Conform		Data producer
Ident. Methyl parahydroxybenzoate	Conform	Conform		Data producer
Methyl parahydroxybenzoate	0,090 - 0,110	0,094	%m/m	Data producer
Assay Sucrose	60,0 - 66,0	63,7	%m/m	Data producer
Total aerobic microbial count (TAMC)	<=1000	Conform	CFU / g	Data producer
Total yeasts and moulds (TYMC)	<=100	Conform	CFU / g	Data producer
E. coli	Negative / gram	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Geen Laboratoria.

Release:  
dr. M.J. Vincenten - van Maanen  
Pharmacist - Qualified Person

02/24/20

Expiration: 06-2021

Conclusion: APPROVED

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