

CERTIFICATE OF ANALYSIS

Batch: 25C13-H100905294

Product: Xanthaangom Excipients 1L

Production date: 13 MAR 2025

Expiry date: 13 MAR 2028

Analyzed according to: HeW Pharma Internal Procedure and Ph. Eur.

Analysis performed on: 02 APR 2025

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Characters		
Colourless, viscous liquid	COMPLIES	COMPLIES
Identifications		
Methyl paraben (HPLC)	POSITIVE	POSITIVE
Propyl paraben (HPLC)	POSITIVE	POSITIVE
Other tests		
pH (Ph. Eur. 2.2.3)	5.5 – 8.5	6.0
Assay		
Methyl paraben (HPLC)	1.34 – 1.64 mg/g	1.46 mg/g
Propyl paraben (HPLC)	0.268 – 0.327 mg/g	0.326 mg/g
Microbiology		
TAMC (Ph. Eur. 2.6.12)	NMT 10^4 CFU/mL	< 1000 CFU/mL
TYMC (Ph. Eur. 2.6.12)	NMT 10^2 CFU/mL	< 10 CFU/mL
Bile-tolerant G- bacteria (Ph. Eur. 2.6.13)	NMT 10^2 CFU/mL	< 10 CFU/mL
Exclusion S. aureus (Ph. Eur. 2.6.13)	ABSENT	ABSENT
Exclusion Salmonella (Ph. Eur. 2.6.13)	ABSENT	ABSENT
Exclusion E. coli (Ph. Eur. 2.6.13)	ABSENT	ABSENT

Conclusion:

The batch complies with the specifications of the performed analysis and is thereby released.

BATCH RELEASED BY:

Ammar Kurdi

Responsible Pharmacist

Release date:

23 APR 2025

