

## CERTIFICATE OF ANALYSIS

Batch: 24J21-F100934071

Product: Xanthaangom Excipiens 1L

Production date: 21 OKT 2024

Expiry date: 21 OKT 2027

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

Analysis performed on: 21 NOV 2024 finalization date

### PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
<b>Characters</b>		
Colourless, viscous liquid	COMPLIES	COMPLIES
<b>Identifications</b>		
Methyl paraben (HPLC)	POSITIVE	POSITIVE
Propyl paraben (HPLC)	POSITIVE	POSITIVE
<b>Other tests</b>		
pH (Ph. Eur. 2.2.3)	5.5 – 8.5	6.0
<b>Assay</b>		
Methyl paraben (HPLC)	1.34 – 1.64 mg/g	1.40 mg/g
Propyl paraben (HPLC)	0.268 – 0.327 mg/g	0.275 mg/g
<b>Microbiology</b>		
TAMC (Ph. Eur. 2.6.12)	NMT 10 <sup>4</sup> CFU/mL	< 1000 CFU/mL
TYMC (Ph. Eur. 2.6.12)	NMT 10 <sup>2</sup> CFU/mL	< 10 CFU/mL
Bile-tolerant G- bacteria (Ph. Eur. 2.6.13)	NMT 10 <sup>2</sup> 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:

25 NOV 2024

