

Certificate of Analysis

Product code:	5038463	Article no.:	802870
Product:	REGU®-AGE CB		
Lot:	42747501	Manufacturing date:	12-May-2025
Analysis No.:	7442747501	Best use before:	12-May-2028

Tests, Parameters:	Specification:	Results:
Appearance Method ref.: Internal method Visual	yellowish to amber coloured, clear to turbid solution	corresponds
pH Method ref.: EP 2.2.3 Potentiometric	5.3 - 6.3	5.8
Relative density d _{20/20} Method ref.: EP 2.2.5 Digital density meter	1.055 - 1.090	1.069
Refractive index n ₂₅ Method ref.: EP 2.2.6 Digital refractometer	1.366 - 1.375	1.369
Identity by HPTLC Method ref.: Internal method Silicagel 60F254; ninhydrin	characteristic chromatogram; corresponds to reference	corresponds
Collagenase inhibitory activity Method ref.: Internal method Enzymatic assay; photometric	> 10 ColU ¹ / ml	corresponds
Inhibitor activity Method ref.: Internal method Enzymatic assay; photometric	> 5 EIU ² / ml	corresponds
SOD activity Method ref.: Internal method Photometric assay	> 1000 ORU ³ / ml	corresponds

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Tests, Parameters:	Specification:	Results:
Total viable aerobic count: Method ref.: according to EP 2.6.12 Membrane filtration		
- TAMC	≤ 100 CFU / ml	corresponds
- TYMC	≤ 100 CFU / ml	corresponds
Specified microorganisms:	absence in one milliliter	corresponds
Method ref.: according to EP 2.6.13		
- Escherichia coli: absent in 1 ml		
- Pseudomonas aeruginosa: absent in 1 ml		
- Staphylococcus aureus: absent in 1 ml		
- Candida albicans: absent in 1 ml		

Comments: ¹ ... Collagenase Inhibitor Unit (CoIU)
² ... Elastase inhibitor Unit (EIU)
³ ... Oxido-Reductase Unit (ORU)

This lot was analysed and released by our authorized Quality Assurance Department and was found to meet the specifications as given above.

Date of issue: 11.06.2025
 MBR - Version: 4

This document is valid without signature.
 Pentapharm AG
 Quality Assurance