



Patheon Softgels B.V.

2020-11-30 ENT/OQA De Posthoornstraat 7 7

5037

Nederland

Hr. Dr. Florian Wildschek 5004 EA TILBURG florian.wildschek@basf.com

Certificate No 6574 Page 21 of 24

Complies

Certificate of Analysis according to DIN 55350-18-4.2.2

Racemic Ibuprofen Lysinate Material 56477527

Order 3383697651 000010 25KG Fibre drums Delivery 3193794457 000010

Purchase Order/Customer Product# 20182096 Lot

52952 Lot/Qty 750.000 KG 00000000056477527 Total 4500.000 KG Transport **AZ CT 1203**

Test Parameter Requirements UoM Results

Characters

Powder Appearance

Complies Colour White to almost white Complies

Identification

RT of the Major Peak corresponds Identification

to the Ibuprofen Peak of the Standard solution from the HPLC

Assay

Furthermore TLC and optical

Rotation must comply

Solution in water

Opalescence Clear Complies Color: BY Min. 6 7

Optical rotation, 20°C,

589 nm

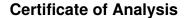
-0.1 to 0.1 0.0 Optical rotation, 20

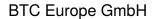
°C, 589 nm

Water (Karl Fischer)

Water (Karl Fischer) Max. 0.5 0.1

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.







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Test Parameter	-	irements	UoM	Results	
Residue on ignition					• • • • • • • • • • • • • • • • • • • •
Residue on ignition	Max.	0.1	%	•	< 0.1
Heavy metals					
Heavy metals, calc. as lead	Max.	10	ppm	•	< 10
Content					
Content (titration) calculated on the anhydrous and solvent-free substance		to 101.5	%		99.9
Content (HPLC)					
Content (HPLC) calculated on the anhydrous and solvent-free substance		to 101.5	%		98.9
Related substances					
Impurities Sum of all impurities		0.10% each 0.3	%		Complie:

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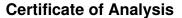
Test Parameter	Requirements	UoM	Results	
Related substances (TL	.C)			
Impurities	Max. 0.1% each			Complies
Residual solvents (GC)				
Ethanol	Max. 1000		ppm	68
Toluene	Max. 890		ppm	11
B				
Particle size (laser d	iiffraction)			
D (50%)	Max. 15		um	9

RESULT: Racemic ibuprofen lysin uncomp. (RIBL) meets the requirements of our specification KU 537. Racemic ibuprofen lysin is manufactured according to current GMP requirements.

Related substances (HPLC): Any impurity at a Level greater than (>0.05) the

reporting threshold is reported with RRT and corresponding quantitative result. If no impurities with relative Retention time (RRT) are listed, then no impurities are present above the reporting threshold.

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Production date: (YYYY-MM-DD) 2020-04-28 Release date : (YYYY-MM-DD) 2020-05-27 Retest date : (YYYY-MM-DD) 2024-04-27

: Siegfried PharmaChemikalien Minden GmbH Manufacturer

> 32423 Minden Germany

Site Quality Assurance: Dr.Wienken

BASF SE Quality Assurance - Release sig. Hr. König

QA-Representative

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