Fax No 0031134624139

Patheon Softgels B.V.

De Posthoornstraat 7 7
5037
5004 EA TILBURG

Nederland

2020-11-30
ENT/OQA
Hr. Dr. Florian Wildschek
florian.wildschek@basf.com
Certificate No 6574

Certificate of Analysis according to DIN 55350-18-4.2.2

Racemic Ibuprofen Lysinate

25KG Fibre drums
Purchase Order/Customer Product#
52952
000000000056477527

Material	56477527	
Order	3383697651	000010
Delivery	3193794457	000010
Lot	20182096	
Lot/Qty	750.000	KG
Total	4500.000	KG
Transport	AZ CT 1203	

Test Parameter	Requirements	UoM	Results
Characters			
Appearance	Powder		Complies
Colour	White to almost white		Complies
Identification			
Identification	RT of the Major Peak corresponds to the Ibuprofen Peak of the Standard solution from the HPLC Assay Furthermore TLC and optical Rotation must comply		Complies
Solution in water			
Opalescence	Clear		Complies
Color: BY	Min. 6		7
Optical rotation, 20°C, 589 nm			
Optical rotation, 20 °C, 589 nm	-0.1 to 0.1	°	0.0
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.

BTC
Chemical Distribution

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Test Parameter	Requirements	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	98.5 to 101.5	%	99.9
Content (HPLC)			
Content (HPLC) calculated on the anhydrous and solvent-free substance	98.5 to 101.5	%	98.9
Related substances			
Impurities	Max. 0.10% each		Complies
Sum of all impurities	Max. 0.3	%	< 0.1

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Test Parameter	Requirements	UoM	Results
Related substances (TLC)			
Impurities	Max. 0.1% each		Complies
Residual solvents (GC)			
Ethanol	Max. 1000	ppm	68
Toluene	Max. 890	ppm	11
Particle size (laser diffraction)			
D (50%)	Max. 15	µm	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

Manufacturer : Siegfried PharmaChemikalien Minden GmbH
32423 Minden
Germany
Site Quality Assurance: Dr.Wienken

BASF SE
Quality Assurance - Release
sig. Hr. König
QA-Representative

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