

OFIPHARMA

METAPHARMACEUTICAL

Certificate of analysis

N DE LOTE:

0191224

18/12/20

Product:	GLYCOPYRROLATE		
Batch number:	2411081.1843	Manuf. Batch number:	103623004
Manufacturing date:	May-2023	Expiry date:	May-2028
Quality:	EP 04/2011:1783		

Physical state: Crystalline powder

Colour: White

Odour: Odourless

Solubility: Freely soluble in water, soluble in ethanol (96%). Very slightly soluble in CH₂Cl₂. Practically insoluble in chloroform and in ether.

Test	Requirement	Result	Unit	Standard remark	Control by
Identification					
A. IR spectrum	Positive	Positive			AC Man
B. Bromides	Positive	Positive			AC Man
Tests					
Appearance of solution	Clear, colourless	Complies			AC Man
Loss on drying	≤ 0.5	0.15	%		AC Man
Residue on ignition	≤ 0.1	0.06	%		AC Man
Acidity or alkalinity	Positive	Positive			AC Man
Diastereomer purity					
Erythro diastereomer	≤ 0.2	< 0.025	%	HPLC	AC Man
Organic impurities				HPLC	
Impurity O	≤ 0.10	< 0.00015	%		AC Man
Impurity G	≤ 0.10	< 0.0015	%		AC Man
Impurity J	≤ 0.10	< 0.0015	%		AC Man
Any other individual and unknown impurity	≤ 0.10	0.023	%		AC Man
Total impurities	≤ 0.5	0.054	%		AC Man
Assay					
On dried substance	99.0 – 101.0	99.75	%		AC Man

AC Man = Analysis performed by Manufacturer | AL = Analysis performed by authorized Laboratory
Guaranteed traceability available at Ofipharma

Drenthweg 25, 9561 AZ, Ter Apel, The Netherlands		T: +31 599 745 390	F: +31 599 582 734	E: info@ofipharma.com	
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Test	Requirement	Result	Unit	Standard remark	Control by
Related substances				TLC	
1, 1-dimethyl-3-hydroxy pyrrolidinium bromide	≤ 0.15	< 0.05	%	IH	AC Man
Single other	≤ 0.10	< 0.05	%	IH	AC Man
Residual solvents				GC	
Acetone	≤ 100	< 13	ppm	IH	AC Man
Acetonitrile	≤ 350	215	ppm	IH	AC Man
Toluene	≤ 100	< 6	ppm	IH	AC Man
Particle size					
% over 63 mcm	≤ 55	19.78	%	IH	AC Man
% over 44 mcm	≤ 70	29.27	%	IH	AC Man
% over 37 mcm	≤ 40	33.95	%	IH	AC Man
Density					
Bulk	0.20 – 0.60	0.44	g/ml	IH	AC Man
Tapped	0.50 – 0.90	0.67	g/ml	IH	AC Man
Microbiological tests					
TAMC	≤ 100	< 10	CFU/g		AC Man
TYMC	≤ 10	< 10	CFU/g		AC Man
Bacterial endotoxins	< 20	< 20	EU/mg		AC Man

Storage condition: Store below 30°C (86°F); excursion permitted to 40°C (104°F)

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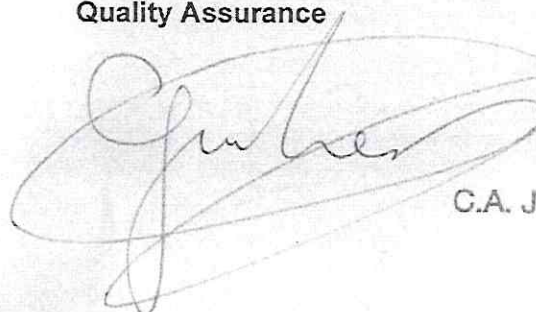
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Other data	Requirement	Result	Standard remark
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform	Data producer
Metallic Residues	Conform CHMP/ICH/353369/2013	Conform	Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform	Data producer
CEP	Available on request R1-CEP 2014-194-Rev 01	Conform	Data producer

Production, expiry/retest date conform primary packaging. I hereby confirm that the above mentioned results are in compliance with the referred Pharmacopoeia and are authentic and accurate.

Conclusion: Approved

Quality Assurance

 11 DEC 2024
C.A. Jonker, MSc

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