

COMO, 28/07/2021				
ANALYSIS No. F118/2021		BATCH No. 103621002		
Manufacturing date: June 2021		Retest date: June 2026		Batch size: 23,82 Kg
PRODUCT		GLYCOPYRROLATE CAS N. 51186-83-5		
Physical State: Crystalline powder		Molecular weight: 398.34		
Colour: White		Formula : C19H28BrNO3		
Odour: Odourless		Method No. 4171 Ed.XVIII		
Solubility: Freely soluble in water, soluble in ethanol (96%). Very slightly soluble in CH ₂ Cl ₂ . Practically insoluble in chloroform and in ether.				
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
I.R. Spectrum	Positive	Positive	Positive	Positive
HPLC	Positive	Positive		Positive
Bromide	Positive	Positive	Positive	Positive
Loss on drying	0.03 %	n.m.t. 0.5%	n.m.t. 0.5%	n.m.t. 0.5%
Appearance of the solution	Clear Colorless		Clear Colorless	Clear Colorless
Acidity or alkalinity	Positive		Positive	Positive
Residue on ignition	0.05 %	n.m.t. 0.3%	n.m.t. 0.1%	n.m.t. 0.1%
Related Substances by TLC				
1,1-dimethyl-3-hydroxy pyrrolidinium bromide	I.t. 0,05%			n.m.t. 0.15%
Single other	I.t. 0,05%			n.m.t. 0.10%
Organic impurities: Procedure 1 USP (HPLC)				
Related Compound A	I.t. 0,00015%	5-nitroisophthalic acid n.m.t. 0.15%	Impurity O n.m.t. 0.10%	n.m.t. 0.10%
Related Compound B	I.t. 0,0015%	Glycopyrrolate base n.m.t. 0.15%	Impurity G n.m.t. 0.10%	n.m.t. 0.10%
Related Compound C	I.t. 0,0015%	Cyclopentylmandelic acid n.m.t. 0.15%	Impurity J n.m.t. 0.10%	n.m.t. 0.10%
Any other individual and unknown impurity	0.037 %	n.m.t. 0.10%	n.m.t. 0.10%	n.m.t. 0.10%
Total impurities	0.088 %	n.m.t. 0.50%	n.m.t. 0.5%	n.m.t. 0.50%



Qualified Person



Quality Control Manager

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Diastereomer purity (HPLC) <i>Erythro diastereomer</i>	I.t. 0,1%	n.m.t. 0.4%	n.m.t. 0.2%	n.m.t. 0.15%
Assay <i>HClO₄ 0.1N on dried substance</i>	100.30 %		min. 99.0% max. 101.0%	min. 99.0% max. 101.0%
Residual Solvents GC <i>Acetone</i> <i>Acetonitrile</i> <i>Toluene</i>	I.t. 13 ppm 340 ppm I.t. 6 ppm			n.m.t. 100 ppm n.m.t. 350 ppm n.m.t. 100 ppm
Particle size <i>% over 63 mcm</i> <i>% over 44 mcm</i> <i>% over 37 mcm</i>	5.28 % 13.05 % 17.77 %			n.m.t. 55% n.m.t. 70% n.m.t. 40%
Bulk density Tapped density	0.41 g/ml 0.60 g/ml			min. 0.20 g/ml max. 0.60 g/ml min. 0.50 g/ml max. 0.90 g/ml

Class 1 solvents are absent according to ICHQ3C. This batch was manufactured in compliance with the cGMPs, according to ICH Q7A and to the filed DMF.


Qualified Person

Quality Control Manager
Release date: 24/08/2021