AMSA - ANONIMA MATERIE SINTETICHE & AFFINI S.P.A.
SOCIETÀ CON UNICO SOCIO
CAPITALE SOCIALE € 290.888 INT. VERS.
STAB.: VIA G. DI VITTORIO, 6 22100 COMO TEL. +39 031521360 - FAX +39 031590941
UFF.: VIALE DEL GHISALLO, 20 20151 MILANO TEL. 02.3270483 - TELEFAX: 02.39219957

COMO, 08/06/2023

ANALYSIS No. F115/2023

BATCH No. 103623004

Manufacturing date: **09 May 2023** Retest date: **09 May 2028** Batch size: **76,52 Kg**

PRODUCT **GLYCOPYRROLATE**
CAS N. 51186-83-5

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.

Molecular weight: 398.34
Formula : C19H28BrNO3
Method No. 4171 Ed.XVIII

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	0.15 %	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	0.06 %	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	l.t. 0,05%			n.m.t. 0.15%
Single other	l.t. 0,05%			n.m.t. 0.10%
Organic impurities: Procedure 1 USP (HPLC)				
Related Compound A	l.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	l.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	l.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	0.023 %	n.m.t. 0.10%	n.m.t. 0.10%	n.m.t. 0.10%
Total impurities	0.054 %	n.m.t. 0.50%	n.m.t. 0.5%	n.m.t. 0.50%

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Diastereomer purity (HPLC)				
Erythro diastereomer	l.t. 0,025%	n.m.t. 0.4%	n.m.t. 0.2%	n.m.t. 0.15%
Assay				
HClO4 0.1N on dried substance	99.75 %		min. 99.0% max. 101.0%	min. 99.0% max. 101.0%
Residual Solvents GC				
Acetone	l.t. 13 ppm			n.m.t. 100 ppm
Acetonitrile	215 ppm			n.m.t. 350 ppm
Toluene	l.t. 6 ppm			n.m.t. 100 ppm
Particle size				
% over 63 mcm	19.78 %			n.m.t. 55%
% over 44 mcm	29.27 %			n.m.t. 70%
% over 37 mcm	33.95 %			n.m.t. 40%
Bulk density	0.44 g/ml			min. 0.20 g/ml max. 0.60 g/ml
Tapped density	0.67 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: 28/06/2023