

CURIA Italy S.r.l. – Sole Shareholder

Registered Office: Via del Vecchio Politecnico n. 9, 20121 Milan (MI)

Tax code – Vat Number– Trade Register of Milan n. 10917240961 - R.E.A. MI 2567069 – Share capital € 30.621.335,00



CERTIFICATE of ANALYSIS

Product:

ROCURONIUM BROMIDE

According to USP43-NF38, Ph Eur. 10.0

MANUFACTURING SITE: CURIA Italy S.r.l. – Via Volturmo 41/43 – 20089 Rozzano (MI)

Batch:

IE2200322A

Code:

30114

Manufacturing Date:

May, 2022

Analysis Date:

June, 2022

Re-test Date:

May, 2027

TEST	SPECIFICATIONS	RESULTS
Characters	Almost white or pale yellow, slightly hygroscopic powder	Complies
Identification:		
- IR Spectrum	Must Comply with the Standard	Complies
- HPLC	Must Comply with the Standard	Complies
- Ion Bromide	Positive	Positive
Appearance of Solution	Clear and not more intensely colored than the Reference Solution BY5	Complies
Specific Optical Rotation (on Anhydrous and Solvent Free Basis)	Between +28,5° and +32,0°	30,8 °
Acidity (pH at 25°C)	Between 8,9 and 9,5	9,2
Water (Karl Fischer)	Not More Than 4,0%	2,8 %
Residue on Ignition	Not More Than 0,1%	0,0 %
Assay on Anhydrous Basis (HPLC)	Between 98,0% - 102,0%	98,7 %
Assay on Anhydrous Basis (Titrimetric)	Between 99,0% - 101,0%	99,4 %
Related Compounds HPLC (EP/USP):		
- Impurity A/Related Compound A	Not More Than 0,2%	< DL
- Impurity B/Related Compound B	Not More Than 0,2%	0,1 %
- Impurity C/Related Compound C	Not More Than 0,2%	0,1 %
- Impurity D/Related Compound D	Not More Than 0,10%	n.d.
- Impurity E/Related Compound E	Not More Than 0,10%	n.d.
- Impurity F/Related Compound F	Not More Than 0,1%	0,1 %
- Impurity G/Related Compound G	Not More Than 0,1%	n.d.
- Impurity H/Related Compound H	Not More Than 0,1%	n.d.
- Each Single Unknown (Largest)	Not More Than 0,10%	< DL
- Total Impurities	Not More Than 1,0%	0,2 %
Chlorides*	Not More Than 0,1%	< 0,1 %
Allyl Bromide	Not More Than 10 ppm	n.d.
Related Solvents (HSGC):		
- Ethyl Acetate	Not More Than 5000 ppm	2597 ppm
- Methyl Terbutylether	Not More Than 5000 ppm	73 ppm
- Dichloromethane	Not More Than 600 ppm	202 ppm
- Acetonitrile	Not More Than 410 ppm	n.d.
Microbiological Control:		
- Bacterial Endotoxins	Not More Than 0,7 EU/mg	< 0,35 EU/mg
- TAMC	Not More Than 100 CFU/g	< 10 CFU/g
- TYMC	Not More Than 10 CFU/g	< 10 CFU/g
- Escherichia coli **	Absent/1g	Skip Testing
- Staphylococcus aureus **	Absent/1g	Skip Testing
- Pseudomonas aeruginosa **	Absent/1g	Skip Testing
- Salmonella sp. ***	Absent/10g	Skip Testing
<p>Note:</p> <p>Solubility: Freely soluble in water, very soluble in methylene chloride, freely soluble in anhydrous ethanol</p> <p>* Test carried out by a Qualified External Laboratory</p> <p>** Test Performed on a Skip Testing Basis (Every 5 Batches or at Least Once a Year)</p> <p>*** Test Performed on a Skip Testing Basis (Every 10 Batches or at Least Once a Year)</p>		

Milan - June 13, 2022

QC Supervisor

Stefano Pandolfi

QC Manager

Claudia Caldirola

Production Unit - Milano Area
Via Volturmo 41/43, - 20089 - Rozzano (MI) ITALY
Via Monte Rosa, 114/116 - 20089 - Rozzano (MI) ITALY

Production Unit – Varese Area
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www.curiaglobal.com