

**QUALITY CONTROL
CERTIFICATE OF ANALYSIS**

PRODUIT / Material : **OXYBUTYNIN CHLORIDE USP**

LOT N° : **22032C105**

N°de COMMANDE / Order n° **BE00144**

ANALYSE / Analysis n° : **1503779**

POIDS NET / Net weight : **50 KG 000**

CONDITIONNEMENTS / Packages : **2**

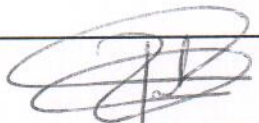
Fabrication / Date of manufacture : **07 - oct. - 2015**

Recontrôle avant / Retest before : **07 - oct. - 2019**

DETERMINATIONS / Tests	SPECIFICATIONS	RESULTATS/Results
APPARENCE (Description)	White crystalline powder	CONFORME
IDENTIFICATION : IR	CONF. A REFERENCE	CONF. A REFERENCE
IDENTIFICATION:HPLC	CONF. A REFERENCE	CONF. A REFERENCE
ID. CHLORURES (Identification, Cl-)	CONFORME	CONFORME
COLORATION DE LA SOLUTION (Color of solution)	max. JB5	<JB5
LIMPIDITE DE LA SOLUTION (Clarity of solution)	CONFORME	CONFORME
ANGLE ROTATION OPTIQUE (optical rotation)	(-) 0.10° - (+) 0.10°	0.00
DEBUT DE FUSION (Melting range, start.)	124 - 129 °C	125.2 °C
FIN DE FUSION (Melting range, end)	124 - 129 °C	128.1 °C
PERTE A LA DESSICCATION (Loss on drying)	0.0 - 3.0 %	0.7 %
CENDRES SULFURIQUES (Sulphated ashes)	0.0 - 0.1 %	0.05 %
METAUX LOURDS (Heavy metals)	<20 ppm	< 20 ppm
HPLC: CYCLOHEXYNYL analogue (Imp A Ph.Eur.)	0.0 - 0.2 %	0.00 %
HPLC:AUTRE IMP. PRINC.(Other single impurity)	0.00 - 0.10 %	0.04 %
HPLC:CHMA	0.00 - 0.15 %	0.00 %
HPLC:CHMME	0.00 - 0.10 %	0.01 %
HPLC:IMP.TOTALES (Total impurities)	0.0 - 0.5 %	0.21 %
HPLC:METHYL ETHYL analogue (Imp C RRT 0.9)	0.00 - 0.10 %	0.04 %
DOSAGE CHLORURE (Chloride content)	8.0 - 10.0 %	8.9 %
DOSAGE (Assay)	99.0 - 102.0 %	99.1 %
SOLVANT RESIDUEL(Heptane)	0 - 500 ppm	0 ppm
SOLVANT RESIDUEL(Methanol)	0 - 500 ppm	3 ppm
GRANULOMETRIE LASER < 100µm (PSD,<100µ)	min.95 %	97 %
GRANULOMETRIE LASER < 40µm (PSD,<40µ)	min.60 %	70 %
GRANULOMETRIE LASER < 80µm (PSD,<80µ)	min.85 %	94 %

Date de contrôle / Date of analysis:08 - oct. - 2015

This product conforms to current USP and current EP.
Manufactured in accordance with ICH Q7 GMP's


Xavier ROBERT
Quality Manager

DATE : 14 octobre 2015

PCAS(Seloc France site)
F-78520 - LIMAY