

Chargenzertifikat / Analysenzertifikat



QUALITY CONTROL CERTIFICATE OF ANALYSIS

PRODUIT / Material : OXYBUTYRIN CHLORIDE

LOT N° : 22032E007

N° de COMMANDE / Order n° BR00348

ANALYSE / Analysis n° : 1703113

POIDS NET / Net weight : 25 KG 000

CONDITIONNEMENTS / Packages : 1

Fabrication / Date of manufacture : 11 - oct. - 2017

Recontrôle avant / Retest before : 11 - oct. - 2021

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. J85	<J85
LIMPIDITE DE LA SOLUTION (Clarity of solution)	CONFORME	CONFORME
ANGLE DE ROTATION OPTIQUE (optical rotation)	(-) 0.10° - (+) 0.10°	+0.00
DEBUT DE FUSION (Melting range, start.)	124 - 129 °C	125 °C
FIN DE FUSION (Melting range, end)	124 - 129 °C	128 °C
PERTE A LA DESICCATION (Loss on drying)	0.0 - 3.0 %	1.1 %
CENDRES SULFUREES (Sulfurated ashes)	0.0 - 0.1 %	0.1 %
METALLS LOURDS (Heavy metals)	<20 ppm	<20 ppm
HPLC: CYCLOHEXYL analogue (Imp A Ph. Eur.)	0.0 - 0.2 %	0.00 %
HPLC: AUTRE IMP. PRINC. (Other single impurity)	0.00 - 0.10 %	0.01 %
HPLC: CHMA	0.00 - 0.15 %	0.01 %
HPLC: CHMMP	0.00 - 0.10 %	0.01 %
HPLC: IMP. TOTALES (Total impurities)	0.0 - 0.5 %	0.14 %
HPLC: METHYL ETHYL analogue (Imp C RRT 0.9)	0.00 - 0.10 %	0.06 %
DOSAGE CHLORURE (Chloride content)	8.0 - 10.0 %	8.8 %
DOSAGE (Assay)	99.0 - 102.0 %	99.5 %
SOLVANT RESIDUEL (Heptane)	0 - 500 ppm	0 ppm
SOLVANT RESIDUEL (Methanol)	0 - 500 ppm	0 ppm
GRANULOMETRIE LASER D10% (PSD, 10%)	max. 20 µm	10 µm
GRANULOMETRIE LASER D50% (PSD, 50%)	21 - 65 µm	30 µm
GRANULOMETRIE LASER D90% (PSD, 90%)	max. 140 µm	89 µm

Date de contrôle / Date of analysis: 11 - oct. - 2017

This product conforms current USP and current EP.
Manufactured in accordance with ICH Q7 GMPs.

Xavier ROBERT
Quality Manager

DATE: 23 janvier 2018

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Prüflabor: Simec AG Zolingen
Prüfbericht: C 667B0 / 6.3.2018
C 667B9 / 6.3.2018