



MANUFACTURER
SYNDEM
47 rue de Longvic
21300 CHENOVE
France



CERTIFICATE OF ANALYSIS

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ITEM NUMBER	: 200020
MATERIAL	: OXYBUTYNIN HCl
BATCH No	: 130563
DATE OF MANUFACTURING.....	: 29/JUL/2015
EXPIRY DATE	: 28/JUL/2019
CONTROL REFERENCE	: 41000042581

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TESTS =====	SPECIFICATIONS =====	RESULTS =====
Procedure PRO LCQ 18 006 (USP) current ed and Specification SPC AQC 18 024 ed 7	Compliant	Compliant
Appearance	White to whitish crystalline powder	Compliant
Identification by infrared spectrum	Identical spectrum with reference	Compliant
Identification by HPLC	Retention time conforms to reference standard	Compliant
Heavy metals (according to USP)	< or = 20 ppm	Compliant
Residue on ignition	<= 0.1%	0.0
Loss on drying at 100-105°C (according to USP)	<= 3%	1
Assay of chlorides on dried product	from 8 to 10%	9

The present batch of product has been manufactured, packaged and analysed in accordance with
all applicable current GMP requirements



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TESTS =====	SPECIFICATIONS =====	RESULTS =====
Residual dioxanne content by GC	<= 50 ppm batch result < LOD (LOD =5ppm)	Compliant
Phenylcyclohexylglycolic acid (compound A) content by HPLC (% w/w)	<= 0.5%	0.0
Diphenyl analog of oxybutynin chloride content by HPLC (% w/w)	<= 0.1%	0.0
Compound B of oxybutynin chloride content by HPLC (% w/w)	<= 1.0%	0.0
Compound C of oxybutynin chloride content by HPLC (% w/w)	<= 1.0%	0.0
Cyclohexenyl analog of oxybutynin chloride content by HPLC (% w/w)	<= 1.0%	0.0

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SYNKEM - 47 rue de Longvic - BP 50 - 21301 Chenôve cedex - France - Tél. 33 (0)3 80 44 72 72 - Fax : 33 (0)3 80 44 72 70

Siège social : 47, rue de Longvic - 21300 Chenôve - France - S.A.S. au capital de 8 587 500 euros - RCS Dijon 421 181 819 - TVA FR 92 421 181 819





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TESTS =====	SPECIFICATIONS =====	RESULTS =====
Ethylpropyl analog of oxybutynine chloride content by HPLC (% w/w)	<= 0.1%	0.0
Other individual impurities content by HPLC (% w/w each)	<= 0.1%	0.0
Total of impurities by HPLC (% w/w), according to USP	<= 1.0%	0.0
Assay by HPLC (calculated on dry basis)(% w/w)	from 97.0 to 102.0%	99.4
Water content (Karl Fisher) (w/w)	<= 3.0%	1.4
Residual isopropyl acetate content by GC	<= 100 ppm batch result < LOD (LOD =3ppm)	Compliant
Residual dimethylformamide content by GC, according to USP	<= 100 ppm batch result < LOD (LOD=15ppm)	Compliant

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TESTS =====	SPECIFICATIONS =====	RESULTS =====
Residual toluene content by GC, according to USP	<= 100 ppm batch result < LOD (LOD=15ppm)	Compliant
Residual xylene content by GC, according to USP	<= 200 ppm batch result < LOD (LOD=35ppm)	Compliant
Granulometry : particles > 75 µm	<= 30%	13
Granulometry : particles > 45 µm	<= 50%	45

CONCLUSION : Released

QUALITY ASSURANCE MANAGER :
CARTY Véronique

DATE OF RELEASE : 06/NOV/2015

V. CARTY
20 SEP 2015

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