

1510000418

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OLON S.p.A.
Sede Legale
Strada Rivoltana km. 6/7
Rodano (MI)



CERTIFICATE OF ANALYSIS

Product **TRIHXYPHENIDYL HCl-USP** Code N° **2610950** Batch N° **1510000298**
Current edition

Manufacturing date **Mar 2015** Retesting date (where applicable) **Feb 2020** Expiration date (where applicable)

Analysis Number		P1PF030302			Limits	
Test	Results	M.U.	Min	Max		
Description	Slightly off-white, crystalline powder		White, crystalline powder	Slightly off-white		
Identification						
- IR	Conforms to Standard		Conforms to Standard			
- Chlorides Reaction	Conforms		Conforms			
- HPLC	RI conforms to Standard		RI conforms to Standard			
pH (1% w/v sol.)	6,1		5,2	6,2		
Loss on drying	0,2	%		0,5		
Residue on ignition	0,1	%		0,1		
Heavy metals	<20	ppm		20		
Chloride content	10,4	% dried	10,3	10,7		
Specific Rotation	0,06	°	- 0,10	+ 0,10		
Assay (NaOH)	100,0	% dried	99,0	101,0		
Related Substances TLC						
- Each Impurity	< 0,5	%		0,5		
- Total Impurities	< 1,0	%		1,0		
Assay HPLC	98,6	% dried	98,0	102,0		
Related Substances HPLC						
- EP imp. A (3-piperidylpropionophenone)	<0,02	%		0,5		
- Any other Impurity	<0,02	%		0,10		
- Total Impurities	<0,02	%		0,5		
Particle size						
- d(0,9)	78	µm		100		
Packaging and storage			Preserve in tight containers			

This batch has been manufactured, packaged and tested in accordance with EU GMP Guidelines Volume 4 Part II (ICH Q7A).
Manufacturing site of the Active Pharmaceutical Ingredient: OLON S.p.A. - GARBAGNATE MIL,se

Date
April 01, 2015

Ed01
Reissued on
September 02, 2015

Q.C. Manager (Roberto Quaglia)
07 SET 2015
Reviewed by Qualified Person
[Signature]

Reissued for: Lab. Chile