

Certificate of Analysis

Product : Paroxetine Hydrochloride Hemihydrate Ph. Eur	Batch No. : PH00020220
Mfg. Date : Jan, 2019	Exp. Date : Dec, 2023
Dispatch Quantity : 2 Kg	No. of Containers : 01
Customer name : FAGRON IBERICA S.A.U. SPAIN.	

S. No	Test	Result	Specification
01	Appearance	Almost white crystalline powder	White or almost white, crystalline powder
02	Solubility	Complies	Slightly soluble in water, freely soluble in methanol sparingly soluble in ethanol (96%) and in methylene chloride.
03	Identification		
	A. Infrared absorption	Concordant	The IR spectrum of sample should be concordant with that of Paroxetine Hydrochloride Hemihydrate working standard.
	B. Impurity -D	Complies	The principle peak in the chromatogram obtained with the test solution is similar in retention time and size to the principle peak in the test chromatogram obtained with the reference solution (c)
	C. Water	2.5 %	Should be in the range 2.2 % to 2.7 %
	D. Chlorides	positive	Should be positive
04	Impurity D by HPLC	Below Detectable Limit	Not more than 0.2%
05	Related substances By HPLC		
	Impurity A	Below Quantification Limit	Not more than 0.3 %
	Any other impurity	0.08 %	Not more than 0.10 %
	Total Impurities	0.12 %	Not more than 0.5 %
06	Water by KF	2.5 %	2.2 % to 2.7 %
07	Sulfated ash	0.03 %	Not more than 0.1 %
08	Assay by HPLC (on anhydrous basis)	99.3 %	97.5% to 102.0%
09	Impurity G (by HPLC)	0.05 ppm	Not more than 1ppm
Additional tests			
10	Residual solvents by GCHS		
	Isopropyl alcohol	439 ppm	Not more than 5000 ppm
	Ethyl acetate	Below Detectable Limit	Not more than 5000 ppm
	Methanol	Below Detectable Limit	Not more than 3000 ppm
	Toluene	Below Detectable Limit	Not more than 890 ppm
	Methylene chloride	Below Detectable Limit	Not more than 600 ppm
	Di-Isopropyl ether	Below Quantification Limit	Not more than 430 ppm
	Hexane	48 ppm	Not more than 290 ppm
	Tetra hydro furan	Below Detectable Limit	Not more than 100ppm
	2-Chloropropane	10 ppm	Not more than 98 ppm
11	Specific Optical rotation (0.5 % in alcohol on anhydrous basis)	-85.7°	-83° to -93°
12	Phenol Content	1.0 ppm	Not more than 25 ppm

Remarks: The product complies with Ph. Eur 9.6/CEP No.: R0-CEP 2012-376-Rev 01 Specification.

Prepared by

Reviewed by

Approved by

Asst. Manager-QC

Date: 27/02/2020

Dy. Manager-QC

Date: 27/02/2020

Asst. Manager-QA

Date: 27/02/2020



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PRODUCTES QUÍMICS

TAVERN, 49-51
08006 BARCELONA
C.I.F. B-08100612

FACTURA

Nº Factura : 201072

Data : 26-05-20

F CINCO CABALLEROS

Cinco caballeros, nº 9

14007 CÓRDOBA

Córdoba

C.I.F/N.I.F.: B-14831853

Concepte	Lot	Quant.	Un.	Preu	Import
Comanda: Albarà : 7905 Data : 26-05-20 PAROXETINA HCL	PH0020220	2,00	KG	2.475,000	4.950,00

Import Brut	Ports	Base Imposable	% I.V.A.	Import I.V.A.	Total
4.950,00	0,00	4.950,00	21,0	1.039,50	5.989,50

Forma de pagament: ANTICIPAT

Venciment: 26-05-20

Dades Bancàries :