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CERTIFICATE OF ANALYSIS

PRODUCT CIPROFLOXACIN HYDROCHLORIDE
COMPLIES WITH PH.EUR.

BATCH CIOA5001

Manufacturing Date: 03.2015

Expiry Date: 03.2020

Release Date: 03.2015

TEST	REQUIREMENT	RESULT
DESCRIPTION	White to pale yellow crystalline powder	Conforms
IDENTIFICATION	A).- IR: Positive	Positive
IDENTIFICATION	B).- TLC: Positive	Positive
IDENTIFICATION	C).- Chloride: positive	Conforms
pH (2.5 % w/v in water):	3,5 - 4,5	3,6
WATER (K.F.)	Not more than 6.7 %	6,3 %
SULPHATED ASH	Not more than 0.1 %	0,08 %
HEAVY METALS	Not more than 20 ppm	Conforms
SULPHATES	Not more than 0.04 %	Conforms
CHROMATOGRAPHIC PURITY (TLC)		
Fluoroquinolonic Acid [Ph.Eur. Imp. A]:	Not more than 0.2 %	Not detected
BULK DENSITY	0,20 - 0,60 g/ml	0,32 g/ml
TAPPED DENSITY	0,30 - 0,90 g/ml	0,52 g/ml
APPEARANCE OF SOLUTION (1.25 % w/v in water)	Clear and not more intensely coloured than Ref. Soln. GY5	Conforms
ASSAY (HPLC)	98.0 - 102.0 % (on the anhydrous basis)	100,4 %
RESIDUAL SOLVENTS (GC)		
Isopropyl alcohol:	Not more than 500 ppm	245 ppm
RELATED SUBSTANCES (HPLC)		
Desfluoro compound [Ph.Eur. Imp. B]:	Not more than 0.2 %	0,00 %
Ethylenediamine compound [Ph.Eur. Imp. C]:	Not more than 0.2 %	0,05 %

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