

doxepini HCl Bt 110006 - Al ten x 1100000
10202-Boi



DIPHARMA FRANCIS S.r.l.

Certificate of analysis

Manufacturing site
DIPHARMA FRANCIS S.r.l.
Via Bissone 5
20021 Baranzate MI
Italy

Issued
21.01.2011

Code
500555

Ref. DDT.
8110094

Ref. Order
BI110026

Batch Nr. 1007330
Mfg. date 11.06.2010
Release date 02.07.2010
Retest date 10.08.2015
Analysis nr. 40000035221

Buyer 2000240

FAGRON SERVICES BV
P.O. BOX 120
1910 AC UITGEEST
Netherlands

End User 2000240

FAGRON SERVICES BV

Product

DOXEPIN HYDROCHLORIDE

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Appearance	-	White or almost white crystalline powder.	EP	Conform to description
Identification: melting range	-	Positive	EP	Positive
Identification : UV Absorption	-	Positive	EP	Positive
Identification : IR Spectrum	-	Positive	EP/USP	Positive
Identification : Chlorides	-	Positive	EP/USP	Positive
Identification : HPLC Assay	-	Positive	USP	Positive
Appearance of solution (2%)	-	Clear and colourless	EP	Clear and colourless
Acidity	-	Conform	EP	Conform
Loss on drying	%	max 0,5	EP	0,1
Residue on ignition	%	max 0,1	EP/USP	0,0
Heavy Metals	%	max 0,002	USP	< 0,002
Impurity A EP/USP HPLC	%	max 0,05	EP/USP/Com	< 0,01
Impurity B EP/USP HPLC	%	max 0,10	EP/USP/Com	< 0,00
Impurity C EP/USP HPLC	%	max 0,20	EP/USP/Com	< 0,00
Each other impurity (HPLC)	%	max 0,10	EP/USP/Com	0,01
Total Impurities (HPLC)	%	max 0,3	EP/USP/Com	0,0
Assay (HClO4)	%	98,0 - 101,0	EP	100,0
Doxepin HCl (HPLC)	%	98,0 - 102,0	EP/USP	101,2
(Z)-Isomer (HPLC)	%	13,6 - 18,1	EP/USP	17,2
(E)-Isomer (HPLC)	%	81,4 - 88,2	EP/USP	84,0
Acetone (GC)	µg/g	max 1000	Company	284
Isopropanol (GC)	µg/g	max 100	Company	< 5
Tetrahydrofuran (GC)	µg/g	max 100	Company	< 5
Toluene (GC)	µg/g	max 100	Company	22

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Doxepin Hydrochloride EP USP

Residual Solvents (as per USP 467): We can certify that there is no potential for specific toxic solvents (class 1) to be present and that material, if tested, will comply with established standards.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

UB 02-003

Director Técnico

Quality Control

[Signature]

Quality Assurance

[Signature]