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CAMBREX

Cambrex Profarmaco Milano S.r.L.

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Certificate of Analysis

Product	**LORAZEPAM**	C.A.S. n.	846-49-1
Batch	**281724**	Formula	C15H10Cl2N2O2
Production date	**June 2015**	M.W.	321.2
Expiration Date	**June 2020**	T.S.	011.010
Analysis	**July 3 2015**		
Coa Number	**CA1.838**		

DETERMINATION	SPECIFICATION		RESULT
DESCRIPTION	White or almost white crystalline powder		**COMPLIES**
SOLUBILITY	Acetone	Clear solution	**COMPLIES**
	Methanol	Clear solution	**COMPLIES**
	insolubile in water, sparingly soluble in alcohol slightly soluble in ether and chloroform	Conform	**COMPLIES**
IDENTIFICATIONS	IR spectrum	Conforms to standard	**COMPLIES**
	Rt value by HPLC	Conforms to standard	**COMPLIES**
RESIDUE ON IGNITION		NMT 0.1 %	**0.0**
HEAVY METALS		NMT 20 ppm	**COMPLIES**
LOSS ON DRYING		NMT 0.5 %	**0.1**
pH		4.8 / 7.0	**5.7**
ASSAY (EP)	By volumetric analysis (on dried basis)	98.5 / 101.0 %	**100.9**
ASSAY (USP)	By HPLC (on dried basis)	98.0 / 102.0 %	**99.4**
RELATED SUBSTANCES BY HPLC (EP)	6-Cl-4-(o-ClPh)-2-Quinazoline carboxylic acid (QUINAZOLINE ACID, USP-D)	NMT 0.100 %	**0.004**
	7-Cl-5-(2-ClPh)-1,3-dihydro-2H-1,4-benzodiazepin-2-one 4-oxide (N-OXIDE, EP-C)	NMT 0.100 %	**0.005**
	7-Cl-5-(2-ClPh)-4,5-dihydro-1H-1,4-benzodiazepin-2,3-dione (DIONE, EP-D)	NMT 0.100 %	**0.017**
	7-Cl-5-(2-ClPh)1,3-dihydro-3-acetoxy-2H-1,4-benzodiazepin-2-one (ACETYL-LORAZEPAM, EP-B/USP-A)	NMT 0.100 %	**0.006**
	6-Cl-4-(o-ClPh)-2-Quinazoline carboxaldehyde (QUINAZOLINE ALDEHYDE, EP-E/USP-C)	NMT 0.100 %	**0.038**
	Any unspecified impurity (including Quinazoline alcohol USP-E)	NMT 0.100 %	**0.003**
	Total Impurities	NMT 0.200 %	**0.077**
RELATED SUBSTANCES BY HPLC (USP)	2-NH2-2,5-dichlorobenzophenone (CHLOROKETONE, EP-A, USP-B)	NMT 0.010 %	**ND**
RESIDUAL SOLVENTS BY GLC	Acetone	NMT 100 ppm	**10**
	Toluene	NMT 500 ppm	**44**
	Methylene chloride	NMT 100 ppm	**ND**
PARTICLE SIZE	90%	NMT 30 microns	**21**
	100%	NMT 100 microns	**48**

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7)

The product conforms to requirements of:
USP38 - EuPh8.0

Approved by Qualified Person / Quality Director
Roberto Baima
02-16-2016

This Certificate of Analysis has been approved by the Qualified Person / Quality Director and produced automatically with validated electronic signature