

CERTIFICATE OF ANALYSIS

FLUVOXAMINE MALEATE

**2-[[[(1E)-5-methoxy-1-[4-(trifluoromethyl)phenyl]pentyl-idene]amino]oxy]
ethanamine (Z)-butenedioate**

(C₁₅H₂₁F₃N₂O₂.C₄H₄O₄)

Edition date: **15/05/2014** Quantity: **164,5 kg** Manuf. date: **may-14**

Register n.: **282/14** Batch n.: **247001T01E** Retest date: **may-19**

Analysis date: **15/05/2014** Mol. Weight: **434.4 g/mol** Complies with: **PhEur**

SOLUBILITY: Freely soluble in methanol and ethanol 96%, sparingly soluble in water

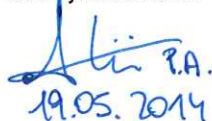
TEST	RESULTS	SPECIFICATIONS
DESCRIPTION	Complies	White or almost white crystalline powder
IDENTIFICATION (IR)	Complies	IR spectrum: according to standard
LOSS ON DRYING	0.03%	Not more than 0.50%
SULPHATED ASH	0.03%	Not more than 0.10%
HEAVY METALS	Complies	Not more than 20 ppm
ASSAY	99.9%	Between 99.0 and 101.0% with reference to the dried substance.
RELATED SUBSTANCES (HPLC)	0.05% Impurity A: not more than 0.20% not detected Impurity B: not more than 0.50% < 0.05% Impurity C: not more than 0.30% < 0.05% Impurity D: not more than 0.15% not detected Impurity F+ G: not more than 0.30% Any unspecified impurity ≤ 0.10% < 0.05% Main impurity 0.05% Sum of all impurities: not more than 1.0%	

"This batch has been produced following current Good Manufacturing Practice (GMP)".

Quality Control


 15.05.2014

Quality Assurance


 19.05.2014

Qualified Person


 19/05/2014

Revision nº9