LOT ACOFARMA: 160360

Manufacturer: Farchemia S.R.L. - 24047 (Italy) Via Bergamo, 121 tel: +39 0363 31401 fax:+39 0363 45985

Certificate of analysis

METRONIDAZOLE USP/EP

code	lot	weight K%	drums n°	delivery n°	manufacturing date	Expiry date	customer code
10051	F150274	50	1	51412568	30.10.2015	27.10.2020	0006

Chemical name: 2-Methyl-5-nitroimidazole-1-ethanol
Empirical Formula: C6 H9 N3 O3
Description: white to pale yellow, crystalline powder
Solubility: slightly sol in H2O, acetone, alcohol, methylene chloride

M.W.: 171,150
CAS: [443-48-1]

TEST	METHOD	RESULTS	UM	SPECIFICATIONS
RESULTS OF ANALYSIS				
USP Tests				
Identification (FTIR absorption)	USP <197A>	Conform		Conform
Identification (HPLC)	USP	Conform		Complies the Ref. Std.
Loss on drying	USP <731>	0.1	%	NMT 0.5 %
Residue on ignition	USP <281>	0.0	%	NMT 0.1 %
Heavy metals	USP Met II <231>	<=0.002	%	NMT 0.005 %
Tinidazole related compound A (HPLC)	USP <621>	0.0	%	NMT 0.1 %
Each unknown impurity (HPLC)	USP <621>	0.00	%	NMT 0.10 %
Total impurities (HPLC)	USP <621>	0.0	%	NMT 0.2 %
Assay (HPLC)	USP <621>	99.2	%	99.0/101.0 %
EUR Tests				
Identification (FTIR)	Ph.Eur. (2.2.24)	Conform		Complies the Ref. Std.
Clarity of solution	Ph.Eur. (2.2.1)	0.5	NTU	NMT 3.0 NTU
Colour of solution	Ph.Eur. (Met. II, 2.2.2)	Conform		NM coloured GY6
Any unknown impurity	Ph.Eur. (2.2.29)	0.00	%	NMT 0.05 %
Related substances (HPLC) any impurity	Ph.Eur. (2.2.29)	0.0	%	NMT 0.1 %
Related substances (HPLC) EP Total imp.	Ph.Eur. (2.2.29)	0.0	%	NMT 0.2 %
Heavy metals	Ph.Eur. (2.4.8)	<=20	ppm	NMT 20 ppm
Loss on drying	Ph.Eur. (2.2.32)	0.1	%	NMT 0.5 %
Sulphated ash	Ph.Eur. (2.4.14)	0.0	%	NMT 0.1 %
Assay (HClO4)	Ph.Eur. (2.2.20)	99.7	%	99.0/101.0 %
Additional tests				
Appearance	FAR	Conform		Conform
pH	Ph.Eur. (2.2.3)	6.5		5.5/7.5
Particle size 10% passing	I-11B-02 5.22	8	µm	
Particle size 50% passing	I-11B-02 5.22	84	µm	
Particle size 90% passing	I-11B-02 5.22	290	µm	
Specific surface area	I-11B-02 5.22	0.31	m²/g	
Foreign matters	I-11B-02 5.26	Conform		Conform

Conform to USP/EP

Note: Referring to GC residual solvents and HPLC results:
Linearity, Precision, Detection and Quantitation Limits are discussed in the corresponding Validation Reports.
Microbiological Tests included in or attached to this CoA are to be considered for information only.

Approved by ..... CASIRATI Maria, QC dir. on 18.02.2016