

CERTIFICATE OF ANALYSIS

issued for Flarer S.A.

EXCELLA
PHARMA SOURCE

Material : BUSPIRONE HYDROCHLORIDE SIEVED	Material no. 9089100
Batch no : 0909588	Page : 2 of 2

Parameter	Unit	n.l.t.	n.m.t.	Result
Characteristics				
Colour		conf.		pass
Identity				
IR spectrum		conf.		pass
Identity HPLC		conf.		pass
Chloride		conf.		pass
Characteristic values				
Melting point	°C	202.0	206.0	203.4
pH-value (USP)		3.0	5.5	4.7
Bulk density (tapped)	g/ml	0.30	0.60	0.45
Purity				
A 5%/5cm at 420 nm	AU		0.100	0.021
Clarity of solution	FTU		3.0	0.3
Water (KF)	%		0.40	0.03
Sulphated ash	%		0.10	0.01
Heavy metals	ppm		20	<20
Related compounds LC				
Impurity A (Ph Eur Imp L)	%		0.10	n.d.
Impurity B (Ph Eur Imp N)	%		0.10	n.d.
Impurity C (Ph Eur Imp C)	%		0.10	n.d.
Buspirone Esteramide (Ph Eur Imp J)	%		0.15	0.06
unknown single	%		0.10	n.d.
total	%		0.2	0.1
Residual solvents				
Acetone	ppm		1000	143
total	ppm		2500	143
Assay				
Chloride	%	8.0	8.8	8.4
Non-aqueous titration	%	99.0	101.0	100.2
Particle size				
Sieve residue 75 µm	%		20	0

conf = conforms to reference standard or testing instruction info = for information only

Summary This material was tested according to the current test procedure, all results meet the specification. This material complies with the required quality.

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