

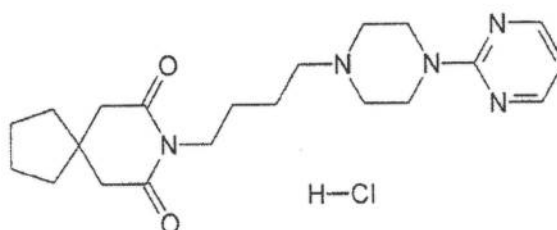
CERTIFICATE OF ANALYSIS

EXCELLA
PHARMA SOURCE

issued for Flarer SA

Material :	BUSPIRONE HYDROCHLORIDE SIEVED	Material no.	9089100
Batch no. :	1208190	Page :	1 of 2

Definition	The following synonyms are used in this document:
Impurity A (Ph.Eur. Imp. L)	8-(4-Chlorobutyl)-8-azaspiro-[4,5]decane-7,9-dione, "Chlorobutyl Buspirone"
Impurity B (Ph.Eur. Imp. N)	1,4-Bis-(8-azaspiro-[4,5]decane-7,9-dione-8-yl)-butane, "Buspirone Dimer"
Impurity C (Ph.Eur. Imp. C)	1,4-Bis(4-(2-pyrimidinyl)piperazine-1-yl)-butane, "Bispyrimidinyl-piperazinyl-butane"
Buspirone Esteramide (Ph.Eur.Imp. J)	4-(7,9-Dioxo-8-azaspiro[4,5]dec-8-yl)butyl-(1-{2-[4-(4 pyrimidin-2yl-piperazinyl)butylamino]-2-oxoethyl}cyclopentyl)acetate



C₂₁H₃₂ClN₅O₂

8-[4-[4-(2-Pyrimidinyl)-1-piperazinyl]butyl]-8-azaspiro[4,5]decane-7,9-dione monohydrochloride

Packaging :	Fibredrum with double PE-bag	Quantity :	10.000 kg
Manufacturing date :	07.Sep.2012	Release date :	04.Oct.2012
CAS-No. :	33386-08-2	Retest date :	07.Sep.2015
Mol. weight :	421.97		
Monograph :	USP , Ph.Eur. , IP		
Characteristics :	white or almost white, crystalline powder		

Remarks The material meets the requirements of the Pharmacopoeial monographs USP <467> and EP 5.4 "Residual Solvents". If not specified, class 1 solvents are not used in the manufacturing process nor could they be introduced during storage and handling of the material. Class 2 and 3 solvents likely to be present are listed in the specification and reported on the CoA.

Commercials -

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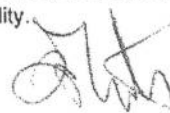
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Material :	BUSPIRONE HYDROCHLORIDE SIEVED	Material no.	9089100
Batch no. :	1208190	Page :	2 of 2

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	203.2
pH-value (USP)		3.0	5.5	4.7
Bulk density (tapped)	g/ml	0.30	0.60	0.39
Purity				
A 5%/5cm at 420 nm	AU		0.100	0.004
Clarity of solution	FTU		3.0	0.3
Water (KF)	%		0.40	0.04
Sulphated ash	%		0.10	<0.01
Heavy metals	ppm		20	<20
Related compounds LC				
Impurity A (Ph.Eur. Imp. L)	%		0.10	<0.01
Impurity B (Ph.Eur. Imp. N)	%		0.10	<0.01
Impurity C (Ph.Eur. Imp. C)	%		0.10	<0.01
Buspirone Esteramide (Ph.Eur. Imp. J)	%		0.15	0.04
unknown single	%		0.10	0.02
total	%		0.2	0.1
Residual solvents				
Acetone	ppm		1000	221
total	ppm		2500	222
Assay				
Non-aqueous titration	%	99.0	101.0	99.9
Particle size				
Sieve residue 75 µm	%		20	<1

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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QC Manager D. Mertins