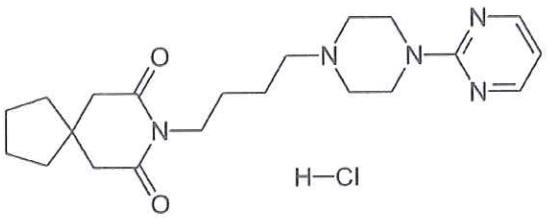
EXCELLA
PHARMA SOURCE
FAREVA

CERTIFICATE OF ANALYSIS

issued for **Flarer SA / Order no. 1002142578**

Material :	**BUSPIRONE HYDROCHLORIDE SIEVED**	Material no.	**9089100**
Batch no. :	**1513611**	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-µl)butyl-(1-{2-[4-(4 pyrimidin-2µl-piperazinyl)butylamino]-2-oxoethyl}cyclopentyl)acetate



$C_{21}H_{32}ClN_5O_2$

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 kg
Manufacturing date :	14.Dec.2015	Release date :	23.Dec.2015	Retest date :	14.Dec.2018
CAS-No. :	33386-08-2				
Mol. weight :	421.97				
Monograph :	USP , Ph.Eur. , IP				
Tested according :	43000/950/93/29				
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.

Retest date is based on data for storage conditions 25°C/60%r.H.!

Commercials -

EXCELLA
PHARMA SOURCE
FAREVA

CERTIFICATE OF ANALYSIS

issued for **Flarer SA / Order no. 1002142578**

Material :	**BUSPIRONE HYDROCHLORIDE SIEVED**	Material no.	**9089100**
Batch no. :	**1513611**	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	203.9
pH-value (USP)		3.0	5.5	4.7
Bulk density (tapped)	g/ml	0.30	0.60	0.47
Purity				
A 5%/5cm at 420 nm	AU		0.100	0.004
Clarity of solution	FTU		3.0	0.3
Water (KF)	%		0.40	0.02
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	0.06
unknown single	%		0.10	0.01
total	%		0.2	0.1
Residual solvents				
Acetone	ppm		1000	111
total	ppm		2500	112
Assay				
Non-aqueous titration	%	99.0	101.0	100.0
Particle size				
Sieve residue 75 µm	%		20	<1

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

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

Printing date 07.01.2016 QC Manager D. Mertins