

CERTIFICATE OF ANALYSIS

issued for Flarer S.A.

EXCELLA
PHARMA SOURCE

Material : BUSPIRONE HYDROCHLORIDE SIEVED	Material no 9089100
Batch no : 0909588	Page : 1 of 2

Definition

Impurity A (Ph Eur Imp. L)

Impurity B (Ph Eur Imp. N)

Impurity C (Ph Eur Imp. C)

Buspirone Esteramide

(Ph.Eur Imp. J)

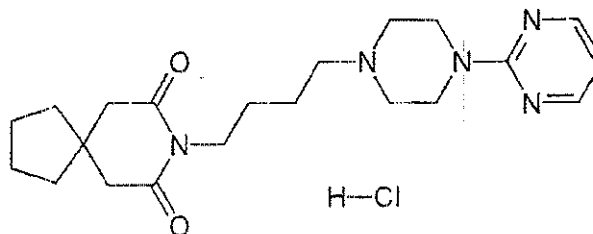
The following synonyms are used in this document:

8-(4-Chlorobutyl)-8-azaspiro-[4.5]decane-7,9-dione, "Chlorobutyl Buspirone"

1,4-Bis-(8-azaspiro-[4.5]decane-7,9-dione-8-yl)-butane "Buspirone Dimer"

1,4-Bis(4-(2-pyrimidinyl)piperazine-1-yl)-butane "Bispyrimidinyl-piperazinyl-butane"

4-(7,9-Dioxo-8-azaspiro[4,5]dec-8-yl)butyl-(1-(2-[4-(4-pyrimidin-2-yl-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 :	Oct 2009	Release date :	27 10 2009
		Retest date :	Oct 2012
CAS-No :	33386-08-2		
Mol. weight :	421.97		
Monograph :	USP, Ph Eur.		
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