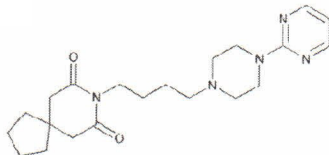


Batch no 2506181
Mf date Jun 18 2025
Retest Jun 17 2028

Molecular Structure



• HCl

Molecular Formula $C_{21}H_{31}N_5O_2 \cdot HCl$
Molecular Weight 421.96
CAS Registry Number 33386-08-2

Aug 05 2025

Tests	Specifications	Results
Appearance	White crystalline powder	Conforms
Solubility	Freely soluble in methanol and in methylene chloride, sparingly soluble in acetonitrile, practically insoluble in hexanes	Conforms
Identification	IR, RRT, Chloride test	Positive
Related substances 240 nm wavelength	Impurity A	$\leq 0.1\%$ < 0.05%
	Spiroammonium salt	$\leq 0.1\%$ < 0.05%
	Bispyrimidinylpiperazinyl butane	$\leq 0.1\%$ < 0.05%
	Bispyrimidinylpiperazinylbutyl ether	$\leq 0.1\%$ < 0.05%
	Buspirone open ring	$\leq 0.3\%$ < 0.05%
	Buspirone open ring dimer	$\leq 0.1\%$ < 0.05%
	Impurity G	$\leq 0.1\%$ < 0.05%
	Buspirone diester dimer	$\leq 0.1\%$ < 0.05%
	Chlorobuspirone	$\leq 0.1\%$ < 0.05%
	Buspirone open ring spirodimer	$\leq 0.2\%$ < 0.05%
	Any other individual impurity	$\leq 0.1\%$ < 0.05%
	Total impurities	$\leq 0.4\%$ < 0.05%
	Impurity K	$\leq 0.1\%$ < 0.05%
	Impurity L	$\leq 0.1\%$ < 0.05%
210 nm wavelength	Buspirone brombutyl analog	$\leq 0.1\%$ < 0.05%
	Impurity N	$\leq 0.1\%$ < 0.05%
	Any other individual impurity	$\leq 0.1\%$ < 0.05%
	Total impurities	$\leq 0.2\%$ < 0.05%
Water determination	$\leq 0.5\%$	0.2%
Residue on ignition	$\leq 0.5\%$	0.04%
Residual solvents	Ethanol	$\leq 0.5\%$ Conforms
	Methyl tertiary butyl ether	$\leq 0.5\%$ Conforms
	Toluene	$\leq 0.089\%$ Conforms
Assay (odb)	97.5 ~ 102.5% of $C_{21}H_{31}N_5O_2 \cdot HCl$	99.3%

Packaging and storage	Preserve in tight, light-resistant containers, at controlled room temperature
Conclusion	Material complies with USP