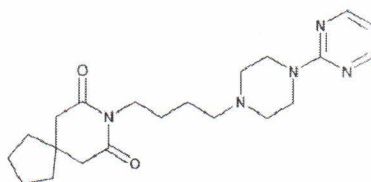


Batch no B27-20230804  
 Mf date Aug 12 2023  
 Retest Jul 2026

### Molecular Structure



• HCl

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

Apr 15 2024

Tests	Specifications	Results
Appearance	White crystalline powder	White crystalline powder
Solubility	Freely soluble in methanol and in methylene chloride, sparingly soluble in acetonitrile, practically insoluble in hexanes	Conforms
Identification	IR, RRT, Chloride test	Positive
Water determination	$\leq 0.5\%$	0.1%
Residue on ignition	$\leq 0.5\%$	0.06%
Related substances	Impurity A $\leq 0.1\%$	$< 0.05\%$
240 nm wavelength	Spiroammonium salt $\leq 0.1\%$	$< 0.05\%$
	Bispyrimidinylpiperazinyl butane $\leq 0.1\%$	$< 0.05\%$
	Bispyrimidinylpiperazinylbutyl ether $\leq 0.1\%$	$< 0.05\%$
	Bupirone open ring $\leq 0.3\%$	$< 0.05\%$
	Bupirone open ring dimer $\leq 0.1\%$	$< 0.05\%$
	Impurity G $\leq 0.1\%$	$< 0.05\%$
	Bupirone diester dimer $\leq 0.1\%$	$< 0.05\%$
	Chlorobupirone $\leq 0.1\%$	$< 0.05\%$
	Bupirone open ring spirodimer $\leq 0.2\%$	$< 0.05\%$
	Any other individual impurity $\leq 0.1\%$	$< 0.05\%$
	Total impurities $\leq 0.4\%$	$< 0.05\%$
210 nm wavelength	Impurity K $\leq 0.1\%$	$< 0.05\%$
	Impurity L $\leq 0.1\%$	$< 0.05\%$
	Bupirone 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 $\leq 0.2\%$	$< 0.05\%$
Assay (odb)	97.5 ~ 102.5% of $C_{21}H_{31}N_5O_2 \cdot HCl$	100.6%

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