Certificate of Analysis

NAME OF PRODUCT : **BUPIVACAINE HYDROCHLORIDE USP**

BATCH NO : **8M56R006**

Mfg Date : **Dec 2008**

Exp Date : **Nov 2013**

TESTS	OBSERVATIONS	STANDARDS
Description	A white crystalline powder	A white crystalline powder
Solubility.	Freely soluble in water and in alcohol. Slightly soluble in chloroform and in acetone	Freely soluble in water and in alcohol. Slightly soluble in chloroform and in acetone
Identification. A IR Spectrum	The IR spectrum is concordant with the standard spectrum of Bupivacaine Hydrochloride.	The IR spectrum must be concordant with the standard spectrum of Bupivacaine Hydrochloride USP.
B. U.V Spectrum	Ultraviolet absorption at 271nm,do not differ by more than 3.0 %	Ultraviolet absorption at 271nm,do not differ by more than 3.0 %
C Test for chlorides	Gives reaction of chlorides	Must Give reaction of chlorides
pH	5.18	Between 4.5 and 6.0
Water	5.20 %	Between 4.0 and 6.0 %
Residue on ignition	0.07 %	Not more than 0.1 %
Heavy metals	Less than 0.001 %	not more than 0.001 %
Limit of residual solvents	Less than 2.0 %	The sum of the content of alcohol and isopropyl alcohol do not exceed 2.0 %
Chromatographic purity: Individual impurity Total impurity	 Less than 0.5 % Less than 2.0 %	 Not more than 0.5 % Not more than 2.0 %
Assay	99.78 %	Must be not les than 98.50 % and not more than 101.5 % calculated with reference to the anhydrous substance.

Conclusion : The sample complies with **USP** Specifications

Final Disposition : Approved	**Disposition by :** SDDay	**Date : 21.01.2009**