

CERTIFICATE OF ANALYSIS

Material Name : **Bupivacaine Hydrochloride B.P.**

Batch. No. **6H56N009**

Mfg. Date : **August 2006**

Exp. Date : **July 2011**

TESTS	OBSERVATIONS	STANDARDS
Appearance	Crystalline powder.	Crystalline powder or crystal.
Colour	Almost white	White or almost white.
Odour	Odourless.	Almost odourless.
Solubility	Complies	Soluble in water, freely soluble in alcohol.
Melting point	255°C	About 254°C
Identification I.R. spectrum	Complies	Must comply with Bupivacaine Hydrochloride CRS.
Chloride	Complies	Must comply.
Acidity / Alkalinity	Complies	Must comply.
Color & Clarity of 2% solution in carbon dioxide free water.	Clear and colorless solution	Must be clear and colorless.
2,6-Dimethylaniline	Less than 100 ppm	Not more than 100 ppm.
Heavy Metals	Less than 10 ppm	Not more than 10 ppm.
Sulphated Ash	0.03%	Not more than 0.1%
Related substances (TLC)	Complies.	Not more than 0.50%.
Loss on drying	5.45 %	4.5% – 6.0%
Assay	99.12%,	98.5% - 101% on dried basis.
Additional Tests :		
Light absorption at 263 nm	0.702	About 0.700.
At 271 nm	0.573	About 0.570.
% Transmission at 430 nm.	99.10%	Not less than 98%
At 530 nm	99.46%	Not less than 98%.
Conclusion : The sample complies with B.P. Specifications		
Final Disposition :	Disposition by	Date : 11-08-2006
APPROVED:	<i>H Singh</i>	