

# Product Specification

## PRODUCT Levobupivacaine Hydrochloride (Min 99%)

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CAS no. [27262-48-2]

$C_{18}H_{29}ClN_2O_1H_2O$

CHARACTERISTICS White or almost white, crystalline powder.  
Soluble in water, freely soluble in alcohol.  
Melting point: about 254 °C.

TEST	SPECIFICATION
Content	99.0% - 101.0% of (dried basis)
Identification	Complies with stated tests
Related substances	Ropivacaine Maximum 0.2% Impurity B Maximum 0.5% Unspecified impurities Maximum 0.1% Total impurities Maximum 0.5%
Appearance of solution	Solution is clear
pH	4.5 to 6.0
Specific optical rotation	-66° to -76°
Water	4.5% to 6.0%
Heavy metals	Maximum 10 ppm
Loss on drying	Maximum 0.5%
Sulphated ash	Maximum 0.1%
2,6 Dimethylaniline (by HPLC)	Maximum 10 ppm
Enantiomeric purity (by HPLC)	(R) Enantiomer Maximum 0.5%
Residual solvents	Acetone Maximum 2000 ppm
Microbiological tests	Complies with stated tests
Bacterial endotoxins	Maximum 0.43 EU/mg

STORAGE Should be stored in an airtight container in a cool, dry place and protected from light.

PRODUCT NAMED ABOVE COMPLIES WITH THE STATED SPECIFICATION.

