

DEVELOP- SPECIFICATION

Material No: **290482**
Buprenorphine Hydrochloride
DEVELOP

CAS No: 53152-21-9
Formula: C₂₉H₄₂ClNO₄
Mol weight: 504.1

Actual specification: 04/24/2007
Last specification: new

Test	Specification	
Description	white or almost white crystalline powder	(Ph.Eur.)
IR-Spectrum	in accordance with the reference spectrum	(Ph.Eur./USP)
Identity (Cl)	chloride positive	(Ph.Eur./USP)
Identity	test B positive	(USP)
Assay (potentiometric.titr.)	98.5 to 101.0 % (calc. on the dried basis)	(Ph.Eur./USP)
Loss on drying	not more than 1.0 %	(Ph.Eur.)
Clarity of solution	not more than 3 FTU	(Ph.Eur.)
Colour of solution	not less than 9 on scale B	(Ph.Eur.)
Acidity or alkalinity	not more than 0.2 ml 0.02 M NaOH or 0.02 M HCl / 0.1 g	(Ph.Eur.)
Specific rotation	-92 to -98 ° (1% [m/V] in MeOH; calc. on the dried basis)	(Ph.Eur.)
Specific rotation	-92 to -98 ° (2% [m/V] in MeOH; calc. on the dried basis)	(USP)
pH value	4.0 to 6.0 (1% [m/V] in H ₂ O)	(USP)
Water (KF)	not more than 1.0 %	(USP)
Residue on ignition	not more than 0.1 %	(USP)
Related substances (HPLC)	not more than 0.15 % Imp. A (Butenylbuprenorphin)	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % Imp. B (Norbuprenorphin)	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % Imp. C (Cyanotertbain)	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % 3-O-Methylbuprenorphin	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % 6-O-Desmethylbuprenorphin	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % 15,16-Didehydrobuprenorphin	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % N-Methylbuprenorphin	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % 7β-Buprenorphin	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.15 % Ethenobuprenorphin	(Ph.Eur./USP)
Related substances (HPLC)	not more than 0.10 % greatest unknown impurity (no unknown impurity greater than 0.10 %)	(Ph.Eur./USP)

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Related substances (HPLC)	not more than 0.65 % sum of all impurities	(Ph.Eur./USP)
Residual solvent	not more than 0.5 % tert-butylmethylether	(Ph.Eur./USP)
Residual solvent	not more than 0.041 % acetonitrile	(Ph.Eur./USP)
Residual solvent	not more than 0.3 % methanol	(Ph.Eur./USP)
Residual solvent	not more than 0.088 % N,N-dimethylformamide	(Ph.Eur./USP)
Residual solvent	not more than 0.5 % diethyl ether	(Ph.Eur./USP)
Residual solvents/ OVI	conformity to CPMP ICH 283/95 and USP test <467>	(Ph.Eur./USP)
