

NADOLOL USP, Ph.Eur.

Product Number: 116640
Batch Number: 1694360
Order Number: 80781721

Date of Manufacture: 14.01.2016
Retest Date: 12.01.2021
Manufacturing site: Fermion Oy, Oulu plant
Specification: European Pharmacopoeia (116640) 07.04.2016

White to off white, practically odorless, crystalline powder Freely soluble in alcohol and in methanol; soluble in water at pH 2; slightly soluble in chloroform, methylenechloride, isopropylalcohol and in water(between pH 7 and pH 10); inso- luble in acetone, benzene, ether, hexane, trichloroethane.

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Identification, IR spectrum	M110384	positive	positive	
Loss on drying	M110385	nmt 2,0 %	0,1 %	
Sulphated ash	M110386	nmt 0,1 %	0,0 %	
Heavy metals Ph Eur	M110387	nmt 30 ppm	nmt 30 ppm	
Racemate composition Aa/Ab	M110384	0,72 - 1,08	0,90	
Organic impurities Ph. Eur., total	M114482	nmt 0,5 %	0,1 %	
Organic impurities Ph. Eur., impurity A	M114482	nmt 0,2 %	0,0 %	
Organic impurities Ph. Eur., impurity D	M114482	nmt 0,2 %	0,1 %	
Organic impurities PhEur,any unspecified	M114482	nmt 0,10 %	<0,05 %	
Assay Ph. Eur, calculated on dried basis	M110394	98,5 % - 101,0 %	99,7 %	
Residual solvents, acetone	M110396	nmt 2000 ppm	1033 ppm	
Residual solvents, toluene	M110396	nmt 200 ppm	<6 ppm	
Residual solvent, methylethylketone	M110396	nmt 200 ppm	<6 ppm	

Fermion Oy

Koivu-Mankkaan tie 6 A, 02200 ESPOO
 P.O.Box 28, FI-02101 ESPOO, FINLAND
 Tel. +358 10 4261
 Fax +358 10 426 4328
 www.fermion.fi

Orioninkatu 2, 10900 HANKO
 P.O.Box 50, FI-10901 HANKO, FINLAND
 Tel. +358 10 4261
 Fax +358 10 426 8223

Lääketehtaan tie 2
 FI-90660 OULU, FINLAND
 Tel. +358 10 4261
 Fax +358 10 426 8429

Fermion Oy. Registered office and domicile: Koivu-Mankkaan tie 6 A, FI-02200 Espoo. VAT Reg No. FI11855212-9

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The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 23.08.2016 08:24:26 by Satu Mattila

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P.O.Box 28, FI-02101 ESPOO, FINLAND

Otonkatu 2, 10900 HANKO
P.O.Box 50, FI-10901 HANKO, FINLAND

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