

**NADOLOL
USP**

Product Number: 116640
Batch Number: 2155118
Order Number: 81227312

Date of Manufacture: 25.05.2023
Retest Date: 23.05.2028
Manufacturing site: Fermion Oy, Oulu plant
Specification: United States Pharmacopeia (116640) 06.04.2023

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, USP, EP	M110384	positive	positive	Fermion Oulu
Identification USP, HPLC	M121964	positive	positive	Fermion Oulu
Loss on drying, USP, EP	M110385	nmt 2,0 %	0,1 %	Fermion Oulu
Resid. on ignition, USP	M110386	nmt 0,1 %	0,0 %	Fermion Oulu
Racemate composition, USP, EP	M110384	40 % - 60 %	47 %	Fermion Oulu
Organic impurities USP, total	M121964	nmt 0,50 %	0,07 %	Fermion Oulu
Organic impurities USP	M121964	nmt 0,20 %	<0,05 %	Fermion Oulu
Nadolol alcohol, impurity A				
Organic impurities USP	M121964	nmt 0,20 %	0,07 %	Fermion Oulu
Nadolol dimer, impurity D				
Organic impurities USP, any unspecified	M121964	nmt 0,10 %	<0,05 %	Fermion Oulu
Assay, calculated on dried basis, USP	M121964	98,0 % - 102,0 %	99,8 %	Fermion Oulu
Residual solvents, acetone	M110396	nmt 2000 ppm	1049 ppm	Turku
Residual solvents, toluene	M110396	nmt 200 ppm	<20 ppm	Turku
Residual solvent, methylethylketone	M110396	nmt 200 ppm	<20 ppm	Turku
Residual solvents, benzene	M110396	nmt 2 ppm	<1 ppm	Turku

Fermion Oy

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Electronically approved 16.06.2023 10:48:36 by Tiia-Riikka Wik

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