

**NADOLOL
USP**

Product Number: 116640
Batch Number: 2222248
Order Number: 81320419

Date of Manufacture: 28.09.2024
Retest Date: 27.09.2029
Manufacturing site: Fermion Oy, Oulu plant
Specification: A.C.E.F. S.p.A. (116640) 05.07.2024

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	Turku
Identification USP, HPLC	M121964	positive	positive	Turku
Loss on drying, USP, EP	M110385	nmt 2,0 %	0,0 %	Turku
Resid. on ignition, USP	M110386	nmt 0,1 %	0,0 %	Turku
Racemate composition, EP	M110384	40 % - 60 %	52 %	Turku
Organic impurities USP, total	M121964	nmt 0,50 %	0,07 %	Turku
Organic impurities USP	M121964	nmt 0,20 %	<0,05 %	Turku
Nadolol alcohol, impurity A				
Organic impurities USP	M121964	nmt 0,20 %	0,07 %	Turku
Nadolol dimer, impurity D				
Organic impurities USP, any unspecified	M121964	nmt 0,10 %	<0,05 %	Turku
Assay, calculated on dried basis, USP	M121964	98,0 % - 102,0 %	99,9 %	Turku
Residual solvents, acetone	M110396	nmt 2000 ppm	829 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
ICHQ7 Compliance	M114580	complies	complies	Fermion Oulu

This batch has been manufactured, packed and tested in accordance with EU

Fermion Oy

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GMP Guideline Volume 4 Part II (ICHQ7)

Electronically approved 15.11.2024 14:30:59 by Janne Eskelinen

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