

NADOLOL USP

Product Number: 116640
Batch Number: 2045142
Order Number: 81075980

Date of Manufacture: 09.04.2021
Retest Date: 08.04.2026
Manufacturing site: Fermion Oy, Oulu plant
Specification: European DMF (116640) 18.03.2021

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
Appearance	M110383	white powder off-white powder	off-white powder	Turku
Identification, IR spectrum, USP, EP	M110384	positive	positive	Turku
Loss on drying, USP, EP	M110385	nmt 2,0 %	0,0 %	Turku
Sulphated ash, EP	M110386	nmt 0,1 %	0,0 %	Turku
Racemate composition, USP, EP	M110384	40 % - 60 %	47 %	Turku
Organic impurities USP, total	M121964	nmt 0,5 %	0,1 %	Turku
Organic impurities USP Nadolol alcohol, impurity A	M121964	nmt 0,15 %	<0,05 %	Turku
Organic impurities USP Nadolol dimer, impurity D	M121964	nmt 0,15 %	0,07 %	Turku
Organic impurities USP, any unspecified	M121964	nmt 0,10 %	<0,05 %	Turku
Assay, calculated on dried basis, EP	M110394	98,5 % - 101,0 %	99,7 %	Turku
Residual solvents, acetone	M110396	nmt 2000 ppm	1107 ppm	Turku
Residual solvents, toluene	M110396	nmt 200 ppm	<6 ppm	Turku
Residual solvent, methylethylketone	M110396	nmt 200 ppm	<6 ppm	Turku

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Electronically approved 29.04.2021 09:42:59 by Tiia-Riikka Wik

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