

NADOLOL USP

Product Number: 116640
Batch Number: 2097769
Order Number: 81148832

Date of Manufacture: 05.04.2022
Retest Date: 04.04.2027
Manufacturing site: Fermion Oy, Oulu plant
Specification: United States Pharmacopeia (116640) 28.03.2022

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, USP, EP	M110384	40 % - 60 %	53 %	Turku
Organic impurities USP, total	M121964	nmt 0,50 %	0,11 %	Turku
Organic impurities USP	M121964	nmt 0,20 %	<0,05 %	Turku
Nadolol alcohol, impurity A				
Organic impurities USP	M121964	nmt 0,20 %	0,11 %	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 %	99,8 %	Turku
Residual solvents, acetone	M110396	nmt 2000 ppm	1403 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

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Electronically approved 05.05.2022 13:02:35 by Anna Hiekkanen

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