

NADOLOL
USP, Ph.Eur.

Product Number: 116640
Batch Number: 1873035
Order Number: 80987160

Date of Manufacture: 13.12.2018
Retest Date: 12.12.2023
Manufacturing site: Fermion Oy, Oulu plant
Specification: United States Pharmacopeia (116640) 05.09.2018

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	Fermion Oulu
Identification USP, HPLC	M121964	positive	positive	Fermion Oulu
Loss on drying	M110385	nmt 2,0 %	0,0 %	Fermion Oulu
Resid. on ignition	M110386	nmt 0,1 %	0,0 %	Fermion Oulu
Racemate composition	M110384	40 % - 60 %	47 %	Fermion Oulu
Elemental impurities, class 1, each	M122036	nmt 1 ppm	nmt 1 ppm	Fermion Oulu
Organic impurities USP, total	M121964	nmt 0,50 %	0,08 %	Fermion Oulu
Organic impurities USP Nadolol alcohol, impurity A	M121964	nmt 0,20 %	<0,05 %	Fermion Oulu
Organic impurities USP Nadolol dimer, impurity D	M121964	nmt 0,20 %	0,08 %	Fermion Oulu
Organic impurities USP, any unspecified	M121964	nmt 0,10 %	<0,05 %	Fermion Oulu
Assay, calculated on dried basis, USP	M121964	98,0 % - 102,0 %	99,3 %	Fermion Oulu
Residual solvents, acetone	M110396	nmt 2000 ppm	1101 ppm	Fermion Oulu
Residual solvents, toluene	M110396	nmt 200 ppm	<6 ppm	Fermion Oulu
Residual solvent, methylethylketone	M110396	nmt 200 ppm	<6 ppm	Fermion Oulu

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

NADOLOL
USP, Ph.Eur.

Product Number: 116640
Batch Number: 1873035
Order Number: 80987160

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
-------	--------	--------------	---------	----------------

Electronically approved 31.01.2019 11:14:23 by Anna Hiekkanen

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

NADOLOL
USP, Ph.Eur.

Product Number: 116640
Batch Number: 1873035
Order Number: 80987160

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
-------	--------	--------------	---------	----------------

Electronically approved 31.01.2019 11:14:23 by Anna Hiekkänen

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