

Lot: 0020915

CERTIFICATE OF ANALYSIS

fermion

NADOLOL USP, Ph.Eur.

Product Number:

116640

Batch Number:

1654087

Manufacturing date:

11.05.2015

Expiry date:

09.05.2020

Manufacturing site:

Fermion Oy, Oulu plant

Delivery:

80649718

Specification:

(116640) 20.12.2011

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); insoluble in acetone, benzene, ether, hexane, trichloroethane.

TESTS	METHOD	REQUIREMENTS	RESULTS
Appearance	M110383	powder	powder
Appearance	M110383	off-white	off-white
Identification, IR spectrum	M110384	white	positive
Loss on drying	M110385	positive	0,0 %
Sulphated ash	M110386	nmt 2,0 %	0,00 %
Heavy metals, PhEur	M110387	nmt 0,10 %	nmt 30 ppm
Racemate composition	M110384	nmt 30 ppm	53 %
Organic impurities, total	M110384	40 - 60 %	0,08 %
Organic impurities, impurity A	M114482	nmt 0,50 %	< 0,05 %
3-(cis-6,7-dihydroxy-5,6,7,8-tetrahydro-1-naphthoxy)-2-hydroxypropanol	M114482	nmt 0,15 %	0,08 %
Organic impurities, impurity D	M114482	nmt 0,15 %	
N,N-bis[3-(cis-6,7-dihydroxy-5,6,7,8-tetrahydro-1-naphthoxy)-2-hydroxypropyl]-terbutylamine			
Organic impurities, any unspecified	M114482	nmt 0,10 %	< 0,05 %
Assay, calculated on dried basis	M110394	98,5 - 101,0 %	99,9 %
Residual solvents, acetone	M110396	nmt 2000 ppm	876 ppm
Residual solvents, toluene	M110396	nmt 200 ppm	< 6 ppm

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NADOLOL USP, Ph.Eur.

Product Number: 116640

Batch Number: 1654087

TESTS	METHOD	REQUIREMENTS	RESULTS
Residual solvent, methyl ethyl ketone	M110396	nmt 200 ppm	< 6 ppm
Approved	28.05.2015	by	Kalle Malmioja

Date and signature: 25.8.2015 T—P—

Tina Peitokorpi
QC Chemist

Fermion Oy

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