

Metapharmaceutcial
C/ Josep Pla 163 2-5
08020 Barcelona
Spain

Date: November 17, 2016

Invoice No. 261111

Your Purchase order No.: No.: 2016 - P/391 dated October 10, 2016
Our Sales No.: S261034/P261027
Delivery Terms: CIP air Barcelona, Spain
Payment: Net 60 days
Bankers: Commerzbank AG Muenchen
Swift: COBADEFFXXX
IBAN: DE13700800000710428500

Description of Merchandise	Origin	Amount
500 gm.net Levothyroxine Sodium sieved Batch No 1510982 CAS No.: 25416-65-3 / Tariff No.: 2937 400 00	Germany	EUR 5.000,00
Total payable amount		EUR 5.000,00

All Values In EUR (€)

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81675 München
Nicole Grodzyski
Logistics & Administration
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Executive Board: Roswitha Welthase, Munich
HRB Munich 126814 • VAT No.: DE143838322 • Tax-No.: 143/137/30558
Commerzbank AG, BLZ 700 800 00, Acct.No.7 104 285 00 • Swift: COBADEFFXXX IBAN: DE13700800000710428500



Metapharmaceutcial
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Date: November 15, 2016

PACKING LIST

YOUR ORDER NO.:	No.: 2016 - P/391 dated October 10, 2016
PRODUCT:	Levothyroxine Sodium sieved
QUANTITY:	500 gm.net. net
PACKING:	1 x 500.net carton with active cooling
BATCH NO.:	1510982
MANUFACTURER:	Excella GmbH
COUNTRY OF ORIGIN:	Germany

Flavine Europe GmbH

Certificate of Analysis & Material Safety Data Sheet Attached

Flavine Europe GmbH
Grillparzerstraße 16
81675 München
Tel 089 93 99 67 0
Fax 089 93 99 67 19

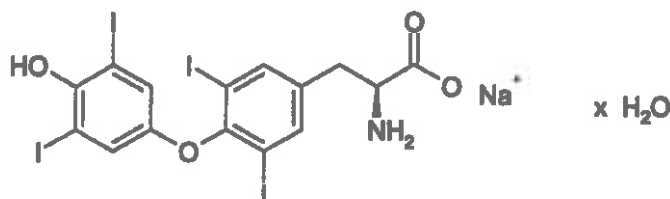
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CERTIFICATE OF ANALYSIS

Issued for **Metapharmaceutical Ind. S.L. / Order no. 1534**

Material :	LEVOTHYROXINE SODIUM	Material no. 9106700
Batch no. :	1510982	Page : 1 of 3

USP Impurities N-Formyl-T4, T4-Acetamide, N-Acetyl-T4, T4-Acetic Acid, Monochlorotriiodothyronine, Lev. N-methylamide, T3-Acetic acid, T6- and T4-amine O-methyl are controlled under the parameter 'unknown single' with 'Related Compounds LC' method.



Sodium (2S)-2-amino-3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]propanoate hydrate

Packaging :	Fibredrum with PE-bag in Alu bag	Quantity : 0.500 kg
Manufacturing date :	09.Nov.2015	Release date : 24.Aug.2016
CAS-No. :	25416-65-3	Retest date : 09.Nov.2018
Mol. weight :	798.85	
Monograph :	USP , Ph.Eur.	
Tested according :	CQK00/190/08/30	
Characteristics :	an almost white or slightly brownish-yellow hygroscopic powder	

Remarks The material meets the requirements of the Pharmacopoeial monographs USP <467> and EP 5.4 "Residual Solvents". Solvents likely to be present are listed in the specification and reported on the CoA. Loss on drying will comply to the Ph.Eur. and USP if tested. Loss on drying is not performed on a routine base because every batch is tested routinely for water (KF) and residual solvents (GC).

Retest date based on data for storage condition +5°CI

Commercial

CERTIFICATE OF ANALYSIS

Issued for **Metapharmaceutical Ind. S.L. / Order no. 1534**

Material :	LEVOTHYROXINE SODIUM	Material no.	9106700
Batch no. :	1510982	Page :	2 of 3

Parameter	Unit	n.l.t.	n.m.t.	Result
Characteristics				
Colour		conf.		pass
Identity				
IR spectrum		conf.		pass
Identity HPLC		conf.		pass
Sodium		conf.		pass
Iodine		conf.		pass
Characteristic values				
Specific rotation	*	18.00	20.00	18.90
Specific rotation (USP)	*	-8.0	-5.0	-5.5
Purity				
Heavy metals	ppm		10	<10
Colour of solution (sol. BY)		3		7
Water (KF)	%	6.00	11.00	8.92
Related compounds LC				
Liothyronine	%		1.0	<0.1
T4-Hydroxyacetic acid/ β -Hydroxy-T4	%		0.30	0.04
T4-Aldehyde	%		0.15	0.01
T4-Benzolic acid	%		0.15	0.01
unknown single	%		0.10	0.06
total	%		1.0	0.3
Related compounds LC 2				
Liothyronine	%		1.0	<0.1
β -Hydroxy-T4	%		0.15	0.02
T4-Hydroxyacetic acid	%		0.15	<0.02
unknown single 2	%		0.10	0.06
total 2	%		2.0	0.2
Microbiological purity				
Total Aerobic Microbial Count (TAMC)	CFU/g		100	<100
Total Yeast and Mould Count (TYMC)	CFU/g		10	<10
Escherichia coli	CFU/g		0	0
Endotoxins (LAL)	EU/ μ g		0.6	<0.1
Residual solvents				
Ethanol	ppm		5000	415
Isopropanol	ppm		5000	<5
Methanol	ppm		3000	<6
N-Butylamine	ppm		300	<15
Pyridine	ppm		200	<4
Trichloroethylene	ppm		80	<9
Acetone	ppm		1000	<3

CERTIFICATE OF ANALYSIS

Issued for **Metapharmaceutical Ind. S.L. / Order no. 1534**

Material :	LEVOTHYROXINE SODIUM	Material no.	9100700
Batch no. :	1510082	Page :	3 of 3

Parameter	Unit	n.l.t.	n.m.t.	Result
Assay				
HPLC	%	97.0	102.0	99.3

conf. = conforms to reference standard or testing instruction, info = for information only

Summary This material was produced and tested under current GMP requirements.
This material was tested according to the current test procedure, all results meet the specification. This material complies with the required quality.

Printing date 15.11.2016

QC Manager P. Muth