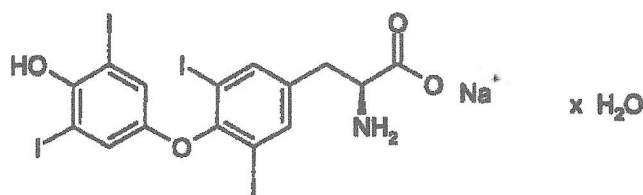


CERTIFICATE OF ANALYSIS

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:	798.86		
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°C

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/μg		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. :	1510982	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.

P. Muth

Printing date 15.11.2016

QC Manager P. Muth