



ANAZB035225

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CERTIFICATE OF ANALYSIS

Order No 4376010447 / 20

Material No 460187

KNGL 000-0000.00

Product LEVOTHYROXINE SODIUM ORAL		
Batch B035225	Manufacture date March 2010	Expiry date March 2015
Tests	Specifications	Results
APPEARANCE	ALMOST WHITE TO FAINTLY BROWNISH YELLOW POWDER	COMPLIES
IDENTIFICATION LEVOTHYROXINE (HPLC)	CORRESPONDING	COMPLIES
IDENTIFICATION LEVOTHYROXINE (COLOUR REACTION, USP-TEST B)	CORRESPONDING	COMPLIES
IDENTIFICATION LEVOTHYROXINE SODIUM (IR-SPECTRUM, PH EUR -TEST B)	CORRESPONDING	COMPLIES
IDENTIFICATION SODIUM (PRECIPITATION REACTION, PH EUR -TEST E)	CORRESPONDING	COMPLIES
IDENTIFICATION IODINE (PYROLYSIS, USP/PH EUR -TEST A/D)	CORRESPONDING	COMPLIES
SPECIFIC OPTICAL ROTATION (USP) WITH REFERENCE TO THE DRIED SUBSTANCE	-6.0 - -5.0 DEGREES	-5,6
SPECIFIC OPTICAL ROTATION (PH EUR) WITH REFERENCE TO THE DRIED SUBSTANCE	16.0 - 20.0 DEGREES	(*)
ABSORPTION MAXIMUM	323 - 327 nm	(*)
SPECIFIC ABSORPTION AT THE MAXIMUM (WITH REFERENCE TO THE DRIED SUBSTANCE)	73.0 - 79.0	(*)
PARTICLE SIZE DISTRIBUTION X (50.3)	NOT MORE THAN 10 micro-m	7
MINIMUM 80%	2 - 20 micro-m	5
MAXIMUM 80%	2 - 20 micro-m	12
LOSS ON DRYING	6.0 - 11.0 %	10,4
CLARITY OF SOLUTION (HYDROCHLORIC ACID/ETHANOL)	CLEAR	COMPLIES
COLOUR OF SOLUTION (HYDROCHLORIC ACID/ETHANOL)	FAINTLY BROWNISH-YELLOW SOLUTION, NOT MORE	COMPLIES

We certify that the above mentioned product conforms with the specifications:

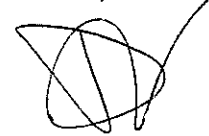
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CP-NO. 1417.16 BP USP PH.EUR.

DATE OF RELEASE 27.04.2010

Sandoz GmbH
A-6250 KUNDL/AUSTRIA

KUNDL, 18.05.2010



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