Exact Copy of Original

V.K. 12 Aug. 19.

19 June 2019

Eli Lilly Kinsale Limited,

Dunderrow, Kinsale, Co. Cork
Telephone 021-4772699
Email kinsale@lilly.com
Fax 021-4775152

Certificate of Analysis

To whom it may concern,

The analysis of this material was conducted according to GMP's and the results demonstrate conformance to the specification for this material.

Material: QA454F
Material Name: Olanzapine Parenteral
Batch Number: C848148
Note: This lot is derived from Olanzapine Final QA402E Parent Lot C764381

Parent Lot QA402E Test Results:

Component	Result	Unit	Acceptance Criteria
Ethyl Acetate (Residual Solvents)	0.12	Percent	Ethyl Acetate (Residual Solvents) <=0.50
Fineness 106 Micron Particle Size	96	Percent Passing	Fineness 106 Micron Particle Size >=90
Fineness 20 Micron Particle Size	36	Percent Passing	Fineness 20 Micron Particle Size >=20 AND Fineness 20 Micron Particle Size <=60
Heavy Metals	PASS - NOT MORE THAN 10PPM		Heavy Metals = "PASS - NOT MORE THAN 10PPM"
Identity (Crystallinity)	PASS - THE X-RAY DIFFRACTION PATTERN MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS.		Identity (Crystallinity) = "PASS - THE X-RAY DIFFRACTION PATTERN MUST COMPARE QUALITITIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS."
Identity (HPLC)	PASS - THE HPLC RETENTION TIME MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS.		Identity (HPLC) = "PASS - THE HPLC RETENTION TIME MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS."
Identity (IR)	PASS - THE IR SPECTRUM MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS.		Identity (IR) = "PASS - THE IR SPECTRUM MUST COMPARE QUALITATIVELY WITH THAT OF THE REFERENCE SAMPLE OBTAINED UNDER THE SAME CONDITIONS."
Largest Individual Related Substance	0.00	Percent	Largest Individual Related Substance[Average]<=0.10
Olanzapine (LSN 170053) Assay	100.0	Percent Volatiles Free	Olanzapine (LSN 170053) Assay >=98.0 AND Olanzapine (LSN 170053) Assay <=102.0
Olanzapine (LSN 170053) Assay	99.8	Percent as is	Olanzapine (LSN 170053) Assay >=98.0 AND Olanzapine (LSN 170053) Assay <=102.0
Physical Appearance (Description)	PASS - IT IS A YELLOW CRYSTALLINE SOLID		Physical Appearance (Description) = "PASS - IT IS A YELLOW CRYSTALLINE SOLID"
Residue On Ignition	0.0	Percent	Residue On Ignition <=0.1
Tin	0	ppm	Tin<=100
Total Related Substances	0.0	Percent	Total related Substances[Average] <=0.2
Water	0.1	Percent	Water[Average] <=1.0

Microbiological Test Results: Olanzapine Parenteral (QA454F)

Description	Conforms		It is a yellow crystalline solid.
Bacterial Endotoxin	<2.0	E.U./mg	Not more than 8.0
Total Aerobic Microbial Count	<10	CFU/G	Not more than 200
Moulds & Yeasts	<10	CFU/G	Not more than 100

Date of Manufacture: 07-May-2017
Release Date: 16-Jan-2018
Retest Date: 06-May-2020

The data contained herein are results obtained by Eli Lilly and Company from tests performed on this product. The Batch was manufactured in compliance with applicable GMPs

Preparer: Valerie Keohane
Printed Name:

V. Keohane
Signature

Date: 19 June 2019
DD-MMM-YYYY

Quality Approver: Caroline O'Driscoll
Printed Name :

CODriscoll
Signature

Date: 19-Jun-2019
DD-MMM-YYYY

Exact Copy of Original

M. 12 Aug, 19