

10-Jan-2020

Lilly, S.A.
Avenida de la Industria, 30
28108 ALCOBENDAS, (Madrid)
Phone:(+34) 91663 50 00

Lilly

Certificate of Analysis

To whom it may concern,

I certify that the below information is a true copy and accurate representation of the data contained within DARWIN.

Material: VL7597001XL3

Material Name: ZYPREXA FINJ 10MG VIAL

Batch Number: D194379

Bulk Batch Number: 199

Country: Chile

Component	Method	Method Type	Result	Unit	Acceptance Criteria
Amide	B04668	HPLC	0.0	Percent	Amide<=0.1
Assay	B04667		99.3	Percent	Assay>=95.0 AND Assay<=105.0
Bacterial Endotoxins	Ph Eur 2.6.14		<7.5	EU/mg	Bacterial Endotoxins<=17.5
Clarity of Solution	Ph Eur 2.2.1	Visual	Pass		Clarity of Solution="Pass"
Colour of Solution	B05927	Visual	Pass		Colour of Solution="Pass"
Crystallinity	B05989		Pass		Crystallinity="Pass"
IR Identity	B07206	IR	Pass		IR Identity="Pass"
Largest Other Individual Related Substance	B04668	HPLC	0.0	Percent	Largest Other Individual Related Substance<=0.1
Particulate Matter	USP <788>		Pass		Particulate Matter="Pass"
pH	B06975	Potentiometric	5.5		pH>=5.4 AND pH<=5.8
Physical Appearance - Olanzapina for Injection 10mg 5ml	APPEARANC E	Visual	Pass		Physical Appearance - Olanzapina for Injection 10mg 5ml="Pass"
Reconstitution Time	B05801	Visual	8	Seconds	Reconstitution Time<=45
Ring Opened Amide	B04668	HPLC	0.1	Percent	Ring Opened Amide <=0.2
Sterility	Ph Eur2.6.1		Pass		Sterility="Pass"
Total Related Substances	B04668	HPLC	0.1	Percent	Total Related Substances<=0.4
Uniformity of Dosage Units	B04667		Pass		Uniformity of Dosage Units="Pass"
Uniformity of Dosage Units - AV	B04667		1.6	Percent	Uniformity of Dosage Units - AV<=15.0
Water	B05332	Karl Fischer	0.4	Percent	Water<=0.6

Date of Manufacture: 24-Sep-2019

Expiration Date: 08 2022

Very truly yours,
Lilly, S.A.

Candelas BARRO
Qualified Person

10 JAN 2020

APPROVAL DATE

Batch Number: D194379

Material: VL7597001XL3

10-Jan-2020

Avenida de la Industria, 30
28108 ALCOBENDAS, (Madrid)
Phone: (+34) 91663 50 00

Lilly

Certificate of Compliance

To whom it may concern,

It is hereby certified that,

Batch: D194379

Material: VL7597001XL3

Material Name: ZYPREXA FINJ 10MG VIAL

Date of Manufacture: 24-Sep-2019

Comments:

Was manufactured by Patheon Italia S.p.A., Viale G.B. Stucchi 110, 20900 Monza, Milano, Italy and packaged by Lilly, S.A., in Alcobendas 28108, Spain.

The manufacture was supervised by trained and qualified personnel in accordance with the EC Guidelines of Good Manufacturing Practices.

All raw and packaging materials were tested and found to comply with all regulatory commitments.

Samples taken from this batch were examined and tested in the analytical laboratories and comply with the registered specification (see attached Certificate of Analysis).

Reference samples from the batch and complete records of the manufacture and testing have been retained and copies would be available if required.

Any deviation from the approved manufacturing process that were made have been completed and the reports would be available in case of need.

The batch has been certified for release for sale by the undersigned who is an authorized Qualified Person according to European Community requirements.

For and on behalf of Lilly, S.A.

Candelas BARRO
Qualified Person

10 JAN 2020

APPROVAL DATE