



Natco Pharma Limited

Regd. Off. : 'NATCO HOUSE', Road No. 2, Banjara Hills,
Hyderabad - 500 034, INDIA.

Tel : +91 40 23547532, Fax : +91 40 23548243



CERTIFICATE OF ANALYSIS

Name of the Product : LETROZOLE			
Grade : Ph.Eur		A.R. No. : CAPI/063/15	
Batch No : LTZ / 0320115		Date of Analysis : 27.01.2015	
Batch Size : 2.260 KG		Retest date : 18.01.2020	
Date of Manufacture : 19.01.2015		Page : 1 of 2	
Inspection Lot No : 040000145419			
S.No	TESTS	RESULTS	SPECIFICATIONS
1.0	Characters 1.1) Appearance 1.2) Solubility	White crystalline powder Complies	White or yellowish, crystalline powder. Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in methanol.
2.0	Identification 2.1) IR Absorption spectrum 2.2) HPLC	Complies Complies	The sample IR spectrum should be concordant with that of working standard IR spectrum. The sample HPLC retention time should be concordant with that of working standard HPLC retention time.
3.0	Related substances (HPLC) a) Impurity A b) Impurity B c) Unspecified impurity d) Total impurities	Not detected Not detected < 0.01 % < 0.05 %	Not more than 0.3 % Not more than 0.1 % Not more than 0.10 % Not more than 0.3 %
4.0	Water (KF)	0.04 %w/w	Not more than 0.3 %w/w
5.0	Assay (HPLC)	99.5 %w/w	Between 98.0%w/w and 102.0%w/w on anhydrous basis
<u>Additional Test(s)</u>			
6.0	Heavy metals	< 10 ppm	Not more than 10 ppm
7.0	Sulfated ash	0.02 %w/w	Not more than 0.1 %w/w
PREPARED BY <i>P. Ravi</i>		CHECKED BY <i>C.K.</i>	APPROVED BY <i>M.C.V. REDDY</i>
Name: <i>V. L. N. S. P. R. A. N. D.</i>		Name: <i>T. Ravi chand</i>	Name: M.C.V. REDDY Dy. Gen. Manager-QC
Date: <i>28-01-15</i>		Date: <i>28-01-15</i>	Date: <i>28-01-15</i>

Chemical Division : (G.P.O. 11001 Certified)

Mekaguda Village, Kothur Mandal, Mahaboobnagar Dt., A.P. Pin : 509 223.

Tel : +91 8548 249493, 249496, Fax : +91 8548 249491



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8.0	Residual solvents a) Methanol b) Dimethyl formamide c) Isopropyl ether d) Hexane e) Isopropyl alcohol f) Acetone g) Methylene chloride h) Chloroform	170 ppm Not detected Not detected Not detected Not detected Not detected Not detected Not detected	Not more than 2000 ppm Not more than 300 ppm Below detection (<1 ppm) Not more than 100 ppm Not more than 100 ppm Not more than 100 ppm Not more than 100 ppm Not more than 60 ppm
9.0	Particle size a) 10% b) 50% c) 90%	2.52 µm 6.56 µm 14.1 µm	Not more than 5 µm Not more than 10 µm Not more than 20 µm
10.0	Microbial limits a) Total Aerobic Microbial count (TAMC) b) Total Yeasts and Moulds Count (TYMC) c) Salmonella d) Staphylococcus aureus e) Escherichia coli f) Pseudomonas aeruginosa	< 10Cfu/g < 10Cfu/g Absent Absent Absent Absent	Not more than 1000cfu/g Not more than 100cfu/g Must be absent Must be absent Must be absent Must be absent
SPECIFICATION REF NO: .NPCD/QA/FP/SP/E047/Old Pharma			
Remarks: The product conforms / Does not conform to the above specifications.			
PREPARED BY <i>P. Ravi</i>		CHECKED BY <i>C.F.</i>	APPROVED BY <i>Rddy</i>
Name: <i>VINUS P. Ravi</i>		Name: <i>P. Ravi Chandra</i>	Name: M.C.V. REDDY Dy. Gen. Manager-QC
Date: <i>28-01-15</i>		Date: <i>28-01-15</i>	Date: <i>28-01-15</i>

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