METAPHARMACEUTICAL

N°DE LOTE: 0100423

Hetero Labs Limited (Unit-I)
Factory : Survey No.10, I.D.A., Gaddapotharam,
Jinnaram Mandal,Sangareddy District-502319,Telangana, INDIA.
Phone : 91-8458-277106, Fax : 91-8458-277135

12/04/2023

CERTIFICATE OF ANALYSIS

Product: ANASTROZOLE					
Batch No.	AL22030002	Reference STP No.	AL-009-02	Analytical Report No.	HL02FP22000644
Reference	Ph.Eur	Date of Manufacture	16-03-2022	Status	Initial Certification
Batch Quantity	6.450 Kg	Date of Analysis	25-03-2022	Retest Date	15-03-2027

S. No.	TEST	RESULT	SPECIFICATION
1	Description (Ref:Visual Inspection)	A white crystalline powder	A white to an off-white crystalline powder.
2	Solubility (Ref:Visual Inspection Ph.Eur 1.4)	Complies	Very slightly soluble in water, Freely soluble in anhydrous ethanol, practically insoluble in Cyclohexane.
3	Identification by		
3.1	Infrared absorption (Ref:Ph.Eur 2.2.24)	Matches with Working standard.	The Infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of Anastrozole Working Standard.
3.2	#HPLC (Ref:Ph.Eur 2.2.29)	Matches with working standard.	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC on anhydrous and solvent free basis test.
4	#XRD (Ref:Ph.Eur 5.9)	Matches with working standard	The X-ray diffractogram of the sample should match with that of Anastrozole (Form-II) Working Standard exhibiting 2 Theta values at about 9.6, 10.9, 12.5, 16.6, 17.1, 18.6, 19.6, 22.1, 22.7, 28.9, 29.3, 30.6, 31.7, 33.6 and 35.2°± 0.2°.
5	Water content (Ref:Ph.Eur 2.5.32)	0.09 % w/w	Not more than 0.30 % w/w
6	#Loss on Drying (Ref.:Ph.Eur 2.2.32)	0.24 % w/w	Not more than 0.50% w/w.
7	Sulphated ash (Ref:Ph.Eur 2.4.14)	0.04 % w/w	Not more than 0.10% w/w.
8	Related Substances by HPLC (Ref:Ph.Eur 2.2.29)		
8.1	% of Individual unspecified Impurity	Below 0.05%	Not more than 0.10%
8.2	% of Total Impurities	0.00 %	Not more than 0.20%
9	Assay by HPLC (On anhydrous and solvent free basis) (Ref: Ph.Eur 2.2.29)	99.9 %w/w	Not less than 98.0 % and Not more than 102.0 %w/w

HETERO LABS LIMITED (UNIT-I) QUALITY ASSURANCE RELEASED 06/03/23

Remarks: APPROVED (Sample Conforms to above Specification)
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Prepared By	Reviewed By	Approved By
BASANI.KRISHNAVENI	RAMESH.MATTA	NAKKANABOINA.VEERRAJU
25-03-2022 16:57	25-03-2022 17:04	25-03-2022 17:08

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10	*Residual Solvents by GC		
10.1	Part-A (Ref: Ph.Eur 2.2.28,5.4 (In-House))		
10.1.1	Methanol	Below LOQ (LOQ:170 ppm)	Not more than 3000 ppm (LOQ:170 ppm)
10.1.2	Isopropyl alcohol	Not Detected	Not more than 5000 ppm (LOQ:90 ppm)
10.1.3	Methylene chloride	Not Detected	Not more than 600 ppm (LOQ:60 ppm)
10.1.4	Tertiarybutylmethylether	19 ppm	Not more than 5000 ppm (LOQ:6 ppm)
10.1.5	n-Hexane	Not Detected	Not more than 290 ppm (LOQ:2 ppm)
10.1.6	Diisopropyl ether	Not Detected	Not more than 100 ppm (LOQ:4 ppm)
10.1.7	Ethyl acetate	Not Detected	Not more than 5000 ppm (LOQ:21 ppm)
10.1.8	Toluene	Not Detected	Not more than 890 ppm (LOQ:8 ppm)
10.2	Part-B (Ref: Ph.Eur 2.2.28, 5.4 (In-House))		
10.2.1	Chloroform	Not Detected	Not more than 60 ppm (LOQ:20 ppm)
10.2.2	Dimethyl formamide	Not Detected	Not more than 880 ppm (LOQ:140 ppm)

HETERO LABS LIMITED (UNIT-I) QUALITY ASSURANCE
RELEASED 26/03/22

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