


**MSN Laboratories Private Limited**

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Factory : Sy. No. 317 &amp; 323, Rudraram (village), Patancheru (Mandal), Medak (District.)

Telangana, Pincode: 502329, India. Phone: +91-8455-305600

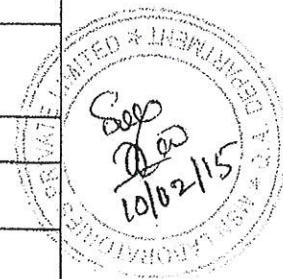
Fax: +91-8455-305689 Alternative Fax: +91-40-30438799

**CERTIFICATE OF ANALYSIS**

Product	: DUTASTERIDE Ph.Eur	Customer name	: Darnax Pharma
Batch No.	: DT0040314	Date of Mfg.	: March 2014
Batch Quantity	: 15.40 Kg	Date of Expiry	: February 2019
A.R.No.	: FP140225	Date of Analysis	: 21.03.2014
Reference	: Ph.Eur	Specification No.	: QC-FPDT-EP/03

Storage: Preserve in well closed containers at controlled room temperature i.e. between 20°C and 25°C (excursions are allowed between 15°C and 30°C).

Sl. No.	TEST	RESULT	SPECIFICATION
1.0	Appearance	Off white colored powder	White or pale yellow powder
2.0	Solubility	Complies	Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol.
3.0	Identification By		
3.1	Specific optical rotation (0.5% soln. in anhydrous ethanol at 589 nm; on anhydrous and solvent free basis)	+37.3°	Between +33.0° and +39.0°
3.2	Infrared spectrum	Complies	The sample infrared absorption spectrum should be concordant with that of the spectrum of standard.
4.0	Related substances by HPLC Method-I		
4.1	Impurity-A	0.01%	Not more than 0.20 %
4.2	Impurity-B	0.004%	Not more than 0.15 %
4.3	Impurity-C	Below Detection limit (0.002%)	Not more than 0.20 %
4.4	Impurity-E	Below Detection limit (0.003%)	Not more than 0.30 %
4.5	Impurity-F	Less than LOQ (0.036%)	Not more than 0.40 %
4.6	Impurity-G	Less than LOQ (0.011%)	Not more than 0.30 %
4.7	Highest individual unspecified impurity	0.03%	Not more than 0.10 %
5.0	Related substances by HPLC Method-II		
5.1	Impurity-H	Not detected	Not more than 0.30 %
5.2	Impurity-I	Not detected	Not more than 0.50 %
5.3	Highest individual unspecified impurity	0.03%	Not more than 0.10 %



Compiled by :

Checked by :

Head, Quality Control :

Date :

Date :

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6.0	Related substances by HPLC Method-III		
6.1	Dihydro Dutasteride	0.07%	Not more than 0.15 %
6.2	β-Isomer	Below Detection limit (0.0060%)	Not more than 0.10 %
6.3	Total impurities (Sum of Method-I, Method-II and Method-III)	0.18%	Not more than 1.50 %
7.0	Water content by coulometry	0.15% w/w	Not more than 0.20 % w/w
8.0	Sulfated ash	0.05%w/w	Not more than 0.10 % w/w
9.0	Assay by HPLC [On anhydrous, Dihydro Dutasteride free and solvent free basis]	99.4%w/w	Not less than 97.0% and Not more than 102.0%w/w
10.0	Residual Solvents by GC		
10.1	Methanol	158 ppm	Not more than 1500 ppm
10.2	Acetonitrile	Less than LOQ (8 ppm)	Not more than 150 ppm
10.3	Dichloromethane	Below Detection limit (7 ppm)	Not more than 100 ppm
10.4	Ethyl acetate	Below Detection limit (2 ppm)	Not more than 500 ppm
10.5	Cyclohexane	79 ppm	Not more than 2000 ppm
10.6	Pyridine	Below Detection limit (7 ppm)	Not more than 100 ppm
10.7	Toluene	Below Detection limit (2 ppm)	Not more than 100 ppm
11.0	Polymorphic identification by PXRD	Complies	The diffractogram of Dutasteride should exhibit the 2-Theta values at 15.72 and 18.11° ± 0.2°.

The product CONFORMS to above specifications

Compiled by: *[Signature]* Checked by: *[Signature]*

Head, Quality Control: *[Signature]*

Date: 10/02/2015 Date: 10/02/2015

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