Letco Medical, LLC.

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CERTIFICATE OF ANALYSIS

Letco Item	697048	697049	697050				
Letco Lot	2403210017	2403210018	2403210019				

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Finasteride USP	NFTD240503	May 19, 2024	May 18, 2029

TEST	SPECIFICATION	RESULT
Description	White to off-white, crystalline solid	Off-white crystalline solid
Identification		
A.	Infrared Absorption	Sample spectrum is similar to that of reference standard.
B.	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.
Specific optical rotation	-56.0° ~ -60.0° (On anhydrous basis)	-58.2°
Water	≤ 0.3%	0.05%
Related substances		
Individual impurity	≤ 0.5%	0.08%
Total impurities	≤ 1.0%	0.24%
Residual Solvents		
Methanol	≤ 3000 ppm	Not detected
Ethanol	≤ 5000 ppm	614 ppm
Methylene chloride	≤ 600 ppm	Not detected
Isopropyl acetate	≤ 5000 ppm	Not detected
Toluene	≤ 890 ppm	Not detected
Residue on ignition	≤ 0.1%	0.04%
Heavy metal	≤ 10 ppm	Conform
Pd	≤ 10 ppm	< 10 ppm
As	≤ 1.5 ppm	< 1.5 ppm
Pb	≤ 0.5 ppm	< 0.5 ppm
Cd	≤ 0.5 ppm	< 0.5 ppm
Hg	≤ 3 ppm	< 3 ppm
V	≤ 10 ppm	< 10 ppm
Co	≤ 5 ppm	< 5 ppm
Ni	≤ 20 ppm	< 20 ppm
Assay	98.5 ~ 101.0% (On anhydrous basis)	99.3%

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

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ADDITIONAL INFORMATION
Letco Medical performed identification testing of this material using a validated method. Manufacturer Conclusion: Complies with the requirements of USP2024 This product is manufactured by Hubei Gedian Humanwell Pharmaceutical Co., Ltd, Gedian Economic Development District, Ezhou, Hubei 436070, China (CHN)

LETCO QA REVIEW: Robin Owens

Digitally signed by Robin Owens
DN: cn=Robin Owens, o=Fagron, ou=Quality Assurance, email=Robin.Owens@Fagron.US, c=US
Date: 2024.07.18 15:57:17 -05'00'

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