



Letco Medical, LLC.

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October 23, 2024	00	1 of 3
CERTIFICATE OF ANALYSIS		

Letco Item:	690192	691773	691774	697756		
Letco Lot:	2407250083	2407250084	2407250085	2407250086		

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Mebendazole USP	MBEX24002A	September 2024	August 2027

TEST	SPECIFICATION	RESULT
Description	White to slightly yellow powder, almost odorless	Slightly yellow powder, almost odorless
* Identification by IR	The infrared absorption spectrum of sample should be concordant with spectrum obtained from Mebendazole standard.	Complies
Polymorph identity by XRD	The Mebendazole sample shows polymorphism. The PXRD of Mebendazole form C should have characteristic 2-Theta values at 4.93 ± 0.2 and 19.80 ± 0.2 .	The Mebendazole sample shows polymorphism. The diffractogram of mebendazole sample shows characteristic 2-Theta values at 4.8933 and 19.7323
* Identification by HPLC	The retention time of sample should be corresponds to that of retention time of standard as obtained in assay by HPLC test.	Complies
Solubility	Freely soluble in formic acid, practically insoluble in water, in dilute solutions of mineral acids, in alcohol, in ether, in methylene chloride and very slightly soluble in chloroform.	Complies
* Loss on drying	Not more than 0.50%	0.153%
* Residue on ignition	Not more than 0.10%	0.042%
Related substances by HPLC		
* Impurity A	Not more than 0.25%	BDL
* Impurity B	Not more than 0.25%	BDL
* Impurity C	Not more than 0.25%	BDL
* Impurity D	Not more than 0.25%	BDL
* Impurity E	Not more than 0.25%	BDL
* Impurity F	Not more than 0.25%	BDL
* Impurity G	Not more than 0.50%	BDL
* Any individual impurity	Not more than 0.10%	BQL
* Total impurities	Not more than 1.0%	Not detected

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



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* Assay by HPLC	Not less than 98.0% and not more than 102.0% on dried basis	100.0%
* Assay by titration	Not less than 99.0% and not more than 101.0% on dried basis	99.7%
Residual Solvents		
* Methanol	Not more than 3000 ppm	165 ppm
* Isopropyl alcohol	Not more than 5000 ppm	BDL
* Methylene chloride	Not more than 600 ppm	BDL
* Xylene	Not more than 2170 ppm	BDL
* Benzene	Not more than 2 ppm	BDL
Particle size (By Malvern)		
d90	For information	60.7 µm
d50	For information	33.2 µm
d10	For information	1.5 µm

LOD/LOQ values for chromatographic purity by HPLC		
Peak Name	LOD	LOQ
Impurity A	0.010%	0.030%
Impurity B	0.010%	0.029%
Impurity C	0.010%	0.030%
Impurity D	0.010%	0.030%
Impurity E	0.010%	0.029%
Impurity F	0.010%	0.030%
Impurity G	0.010%	0.031%
LOD/LOQ values for residual solvents by GC		
Solvent name	LOD (in ppm)	LOQ (in ppm)
Methanol	49.98	151.45
Isopropyl alcohol	50.95	154.38
Methylene chloride	31.08	94.17
Benzene	0.21	0.62
Xylene	107.32	324.7

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ADDITIONAL INFORMATION
<p>* <i>Verification testing performed by Letco Medical is represented by an asterisk.</i></p> <p>Storage Condition: Preserve in well-closed, light-resistant containers. Store at 25°C (Excursions permitted between 15 to 30°C).</p> <p>Manufacturer remarks: The product complies as per USP specification.</p> <p>This product was manufactured by Solara Active Pharma Sciences Limited, Plot Nos. 36, 120 A & B, 120 P & 121 Industrial Area, Baikampady, Mangaluru, Karnataka 575011, India (IND)</p>

LETCO QA REVIEW: _____

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