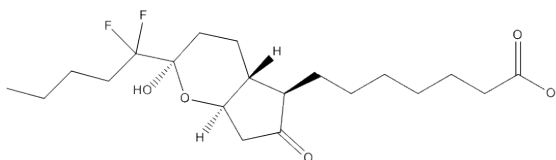


Certificate Of Analysis

Name: Lubiprostone
CAS No.: 333963-40-9
Cat No.: A850935
Molecular Formula: C₂₀H₃₂F₂O₅
Molecular Weight: 390.46
Batch No.: L15082023
Mfg.Date: 2023.08.15
Exp.Date: 2025.08.14



Items	Specifications	Results
Appearance	White crystalline powder	Conforms
Solubility	Insoluble in water and n-hexane, soluble in methanol, acetone, alcohol, ethyl acetate and dichloromethane	Conforms
Identification (HPLC)	Retention time matches with the reference	Conforms
specific rotation	$[\alpha]_{20D}$: - 42.0° ~ - 48.0° (10mg/ml, in methanol, 100mm)	-45.6°
Purity (HPLC)	99%(min)	99.89%
Diastereomers	NMT 0.15%	N.D
Related impurity each(except tautomer)	NMT 0.15%	0.09%
Any unknown impurity	NMT 0.10%	N.D
Total impurity	NMT 0.5%	0.09%
Residue on ignition	NMT 0.1%	0.05%
Residual solvents		
Ethyl Acetate	NMT 5000PPM	1100ppm
n-Heptane	NMT 5000PPM	1200ppm
MTBE	NMT 5000PPM	ND
Ethanol	NMT 5000PPM	ND
Methanol	NMT 3000PPM	ND
THF	NMT 720PPM	ND
DCM	NMT 600PPM	ND

Heavy metals	Palladium : N.M.T. 10ppm	Conforms
Water	N.M.T.0.5 %	0.13%
Assay(anhydrous basis)	98%(min)	99.5%
Particle size distribution	D90: NMT 50um	42.5um
Conclusion	The product tested complies with the specifications.	

Storage condition: Store in a tightly closed container in a cool and dry place.

Checker:

*If you have any comments and suggestions, please contact us by sales@amadischem.com

*For R&D use only