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Certificate of Analysis

Substance name **MTM-010 Drug Substance IBEX MC1**
Abbreviation **MTM-010 DS MC1**

Formula -----
Material 275333

CAS number [---]
Specification BT-61922QA.1
Production date 19-FEB-2021
Expiry date 17-OCT-2021
Analysis date 18-MAR-2021

Sample 3473316
Batch 43002
Customer batch -----

Manufacturing site Lonza AG, Lonzastrasse, 3930 Visp, Switzerland,
Tel +41 27 948 5111, Fax (b) (6), contact.visp@lonza.com

Comment -----
Remark -----

Test	Result	Unit	Specification
Colour	(b) (4)		
BTV101557G.5/1/CHVI-101557.7			
Aspect (visible Particles) Ph.Eur			
BTV101557R.2/1/CHVI-101557.7			
pH of the solution			
BTV082391A.3/1/CHVI-82391.3			
#Endotoxin (USP <85> / EP 2.6.14)			
BT-61922PF.1/1/outsourced.1			
Bioburden (TAMC)			
BT008889TD.3/1/CHVI-8889.7			
Bioburden (TYMC)			
BT008889TD.3/1/CHVI-8889.7			
Osmolality			
BTN050752B.4/1/CHVI-50752.8			
#Identity			
BT-61922PE.1/1			
Total RNA Concentration (AEX-HPLC)			
BT-61922PG.1/1/GROUP-107933.2			
RNA Encapsulation (b) (4)			
BT-61922PD.2/1/GROUP-108245.2			
#Particle size			
BTB109237B.1/1/GROUP-109237.3			
#Polydispersity			
BTB109237B.1/1/GROUP-109237.3			
Lipid Identification, SM-102 (HPLC)			
BTL107937A.4/1/GROUP-107937.2			
Lipid Identification, Cholesterol (HPLC)			
BTL107937A.4/1/GROUP-107937.2			

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Test	Result	Unit	Specification
Lipid Identification, DSPC (HPLC) BTL107937A.4/1/GROUP-107937.2	(b) (4)		
Lipid Identification, PEG2000-DMG (HPLC) BTL107937A.4/1/GROUP-107937.2			
Lipid content, SM-102 (HPLC) BTL107937A.4/1/GROUP-107937.2			
Lipid content, Cholesterol (HPLC) BTL107937A.4/1/GROUP-107937.2			
Lipid content, DSPC (HPLC) BTL107937A.4/1/GROUP-107937.2			
Lipid Content, PEG2000-DMG (HPLC) BTL107937A.4/1/GROUP-107937.2			
Lipid Impurities, all (HPLC) BTL107937A.4/1/GROUP-107937.2			
Lipid Impurities, individual (HPLC) BTL107937B.2/1/GROUP-107937.2			
Lipid Impurities, individual (HPLC) BTL107937B.2/2/GROUP-107937.2			
Lipid Impurities, individual (HPLC) BTL107937B.2/3/GROUP-107937.2			
Lipid Impurities, individual (HPLC) BTL107937B.2/4/GROUP-107937.2			
Relative retention time (HPLC) BTL107937B.2/1/GROUP-107937.2			
Relative retention time (HPLC) BTL107937B.2/2/GROUP-107937.2			
Relative retention time (HPLC) BTL107937B.2/3/GROUP-107937.2			
Relative retention time (HPLC) BTL107937B.2/4/GROUP-107937.2			
IG1, (b) (4) (RP-HPLC) BT-61922PH.2/1/GROUP-107927.2			
Purity, main peak (RP-HPLC) BT-61922PH.2/1/GROUP-107927.2			
IG2, (b) (4) (RP-HPLC) BT-61922PH.2/1/GROUP-107927.2			
IG3, (b) (4) (RP-HPLC) BT-61922PH.2/1/GROUP-107927.2			
For the lab: (b) (6) 19-MAR-2021 (b) (6)			

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Test	Result	Unit	Specification
Restricted Use Batch released by: (b) (6) 20-MAR-2021 (b) (6)	Country specific release according to CR 736000 and CR 759518		

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