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Certificate of Analysis

Substance name	MTM-010 Drug Substance IBEX MC1		
Abbreviation	MTM-010 DS MC1		
Formula	-----	CAS number	[--]
Material	275333	Specification	BT-61922QA.1
Sample	3473319	Production date	24-FEB-2021
Batch	43003	Expiry date	25-MAY-2021
Customer batch	-----	Analysis date	18-MAR-2021
Manufacturing site	Lonza AG, Lonzastrasse, 3930 Visp, Switzerland, Tel +41 27 948 5111, Fax (b) (6) [REDACTED], 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) [REDACTED]			
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			

Continued Certificate of Analysis

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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			
Lipid Impurities, individual (HPLC) BTL107937B.2/5/GROUP-107937.2			
Lipid Impurities, individual (HPLC) BTL107937B.2/6/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			
Relative retention time (HPLC) BTL107937B.2/5/GROUP-107937.2			
Relative retention time (HPLC) BTL107937B.2/6/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			

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Test	Result	Unit	Specification
For the lab: (b) (6) 29-MAR-2021 (b) (6) During the homogeneity validation of this batch, an OOS result was obtained for the lipid concentration (total lipid content and content of the individual lipids) measured on the sample taken at (b) (4) (b) (4) Restricted Use Batch released by: (b) (6) 30-MAR-2021 (b) (6)	See DR 757353 Country specific release according to CR 736000 and CR 759518		

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