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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	3478563	Production date	07-MAR-2021
Batch	43005	Expiry date	05-JUN-2021
Customer batch	-----	Analysis date	25-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			

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Sample 3478563
 Batch 43005
 Customer batch - - - - -

Production date 07-MAR-2021
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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			
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) 31-MAR-2021 (b) (6) Sucrose used as raw material to produce buffers for this batch is involved in an ongoing endotoxin OOS laboratory investigation (results not yet confirmed). The product quality assessment carried out showed that the endotoxin results of (b) (4) (b) (4) were within specification and showed no trend. Based on this, an adverse impact on the product quality of this batch and a risk to patient safety can be excluded. The batch was released based on these conclusions. Restricted Use Batch released by: (b) (6) 01-APR-2021 (b) (6)	See DR TW number 765137 Country specific release according to CR 736000 and CR 759518		

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This certificate is the output of protected data and is signed electronically in compliance with the law.