

LGO	Document ID: MBR-0001	Version: 1.0	Effective Date: 01AUG2021	Process Stage: Drug Product
	Drug Substance Name	Batch number	Drug Substance Number	Site
	New Product 002	B002	DS001	E001

1. Virus filtration

STEP	DESCRIPTION	RECORDED PARAMETER		RESULTS			
1.1	Obtain virus filter. Record Filter lot number and expiry.	Filter Lot Number:		XP5003T122			
		Expiry:		15AUG22			
1.2	Inspect the filter for irregularities	Visual Inspection		<input type="checkbox"/> Pass <input checked="" type="checkbox"/> Fail			
1.3	Remove Product from freezer	Thaw Time Start	Date	11 JUN 21			
			Time	10 : 28 AM (PM)			
		Thaw Time End	Date	13 JUN 21			
			Time	09 : 21 AM (PM)			
		Calculate Total Hold Days(< 7 days at Freezer)		2			
		Thaw Time within the specification:		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail			
1.4	Measure Conductivity	Recorded Conductivity (mS/cm)		51			
		Conductivity within the specification: (3.5-6.5 mS/cm)		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail			
			Parameter	Value	Measurement		
1.5	Measure pH	Measure pH during the six times every hour after thaw took place. Record information on the right. (7.0-7.4)	pH Measurement 1	7.3	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
			pH Measurement 2	7.2 7.1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
			pH Measurement 3	7.1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
			pH Measurement 4	7.1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
			pH Measurement 5	7.2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
			pH Measurement 6	7.2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
PERFORMED BY (INITIAL & DATE):			JMZ	12 JUN 21	13 JUN 21		
VERIFIED BY (INITIAL & DATE):			JMZ	13 JUN 21	13 JUN 21		

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