

LOGO	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 001	6001	DS001	US01

## 1. Virus filtration

STEP	DESCRIPTION	RECORDED PARAMETER		RESULTS			
1.1	Obtain virus filter. Record Filter lot number and expiry.	Filter Lot Number:		XP5003T121			
		Expiry:		19 AUG 22			
1.2	Inspect the filter for irregularities	Visual Inspection		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail			
1.3	Remove Product from freezer	Thaw Time Start	Date	10 JUN 21			
			Time	10 : 33 (AM/PM)			
		Thaw Time End	Date	12 JUN 21			
			Time	09 : 15 (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			
1.4	Measure Conductivity	Recorded Conductivity (mS/cm)		5.5			
		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	7.1	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		
			pH Measurement 3	7.0	<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	7.1	<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 12JUN21			
VERIFIED BY (INITIAL & DATE):				RR 12JUN21			

① Incorrect Entry. Hold time within Range 12JUN21