

Table All

Material Number	Sample Stage	Result Name	Unit	Specificatio..	# of Batches per P..	# of Batches inclu..	# of Batches exclu..	Ppk	Mean Value	Color Ppk
20000019	DP_B-IPC6	ALC-0159 content	mg/mL	MIN <= Res..	19.0	17.0	2.0	0.60	0.19	adequate performance
		ALC-0315 content	mg/mL	MIN <= Res..	19.0	15.0	4.0	0.49	1.25	
		Appearance (Visible..	-	Equal to	19.0	14.0	5.0			low performance
		Bacterial Endotoxin	EU/mL	Result <= M..	19.0	12.0	7.0	1.22	9.22	
		Cholesterol content	mg/mL	MIN <= Res..	19.0	11.0	8.0	0.25	0.70	no Ppk
		DSPC content	mg/mL	MIN <= Res..	19.0	14.0	5.0	0.38	0.33	
		Lipid identities	-	Equal to	19.0	14.0	5.0			adequate performance
		LNP Polydispersity	-	Result <= M..	19.0	14.0	5.0	0.80	0.11	
		LNP Size	nm	MIN <= Res..	19.0	14.0	5.0	0.38	81.43	low performance
		Osmolality	mOsmol/kg	MIN <= Res..	19.0	14.0	5.0	0.58	316.07	
		pH	-	MIN <= Res..	19.0	14.0	5.0	0.62	7.37	no Ppk
		RNA content	mg/mL	MIN <= Res..	19.0	14.0	5.0	0.41	0.09	
		RNA Encapsulation	%	Result >= M..	19.0	14.0	5.0	0.42	91.21	adequate performance
		RNA Integrity	%	Result >= M..	19.0	14.0	5.0	0.25	63.43	
		TAMC	CFU/100mL	Result <= M..	19.0	14.0	5.0	0.55	6.71	low performance
		TYMC	CFU/100mL	Result <= M..	19.0	14.0	5.0	0.70	5.93	
	FLT_F-IPC5	ALC-0159 content	mg/mL	Null	19.0	14.0	5.0		5.35	no Ppk
		ALC-0315 content	mg/mL	Null	19.0	14.0	5.0		5.45	
		Cholesterol content	mg/mL	Null	19.0	14.0	5.0		3.99	adequate performance
		DSPC content	mg/mL	Null	19.0	14.0	5.0		6.03	
		LNP Polydispersity	-	Null	19.0	14.0	5.0		5.84	no Ppk
		LNP Size	nm	Null	19.0	14.0	5.0		6.50	
		RNA content	mg/mL	Result >= M..	19.0	14.0	5.0	0.16	1.80	low performance
		RNA Encapsulation	%	Null	19.0	14.0	5.0		2.19	
	LNP_C-IPC3	RNA Integrity	%	Null	19.0	14.0	5.0		6.47	no Ppk
		ALC-0159 content	mg/mL	Null	19.0	14.0	5.0		4.46	
		ALC-0315 content	mg/mL	Null	19.0	14.0	5.0		4.22	adequate performance
		Cholesterol content	mg/mL	Null	19.0	14.0	5.0		2.73	
		DSPC content	mg/mL	Null	19.0	14.0	5.0		6.04	no Ppk
		LNP Polydispersity	-	Null	19.0	14.0	5.0		4.14	
		LNP Size	nm	Null	19.0	14.0	5.0		5.11	adequate performance
		RNA content	mg/mL	Null	19.0	14.0	5.0		4.09	
	TFF2_RE-IP..	RNA Encapsulation	%	Null	19.0	14.0	5.0		4.19	no Ppk
		RNA Integrity	%	Null	19.0	14.0	5.0		5.46	
		ALC-0159 content	mg/mL	Null	19.0	14.0	5.0		5.94	adequate performance
		ALC-0315 content	mg/mL	Null	19.0	14.0	5.0		5.26	
		Bacterial Endotoxin	EU/mL	Result <= M..	19.0	14.0	5.0	0.47	25.29	low performance
		Cholesterol content	mg/mL	Null	19.0	14.0	5.0		5.06	
		DSPC content	mg/mL	Null	19.0	14.0	5.0		6.21	no Ppk
		LNP Polydispersity	-	Null	19.0	14.0	5.0		6.49	
		LNP Size	nm	Null	19.0	14.0	5.0		5.80	adequate performance
		RNA content	mg/mL	Null	19.0	14.0	5.0		6.65	
		RNA Encapsulation	%	Null	19.0	14.0	5.0		5.99	no Ppk
		RNA Integrity	%	Null	19.0	14.0	5.0		4.91	
		TAMC	CFU/10mL	Result <= M..	19.0	14.0	5.0	0.69	5.93	low performance
		TYMC	CFU/10mL	Result <= M..	19.0	14.0	5.0	0.70	5.29	

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Material Number	Sample Stage	Result Name	Unit	Specificatio..	Standard Deviation	LCL	UCL	LSL	USL	Color Ppk
20000019	DP_B-IPC6	ALC-0159 content	mg/mL	MIN <= Res..	0.03	0.10	0.28	0.11	0.24	adequate performance
		ALC-0315 content	mg/mL	MIN <= Res..	0.24	0.53	1.98	0.90	1.85	
		Appearance (Visible..	-	Equal to						low performance
		Bacterial Endotoxin	EU/mL	Result <= M..	0.90	6.52	11.91		12.50	
		Cholesterol content	mg/mL	MIN <= Res..	0.11	0.36	1.04	0.36	0.78	no Ppk
		DSPC content	mg/mL	MIN <= Res..	0.07	0.11	0.55	0.18	0.41	
		Lipid identities	-	Equal to						adequate performance
		LNP Polydispersity	-	Result <= M..	0.08	-0.12	0.35		0.30	
		LNP Size	nm	MIN <= Res..	17.05	30.28	132.58	56.00	101.00	low performance
		Osmolality	mOsmol/kg	MIN <= Res..	43.37	185.95	446.19	240.00	400.00	
		pH	-	MIN <= Res..	0.25	6.61	8.13	6.90	7.90	no Ppk
		RNA content	mg/mL	MIN <= Res..	0.01	0.05	0.13	0.08	0.12	
		RNA Encapsulation	%	Result >= M..	4.89	76.56	105.87	85.00		adequate performance
		RNA Integrity	%	Result >= M..	7.38	41.30	85.56	58.00		
		TAMC	CFU/100mL	Result <= M..	1.98	0.78	12.65		10.00	low performance
		TYMC	CFU/100mL	Result <= M..	1.94	0.11	11.75		10.00	
	FLT_F-IPC5	ALC-0159 content	mg/mL	Null	3.80	-6.06	16.76			no Ppk
		ALC-0315 content	mg/mL	Null	4.32	-7.51	18.41			
		Cholesterol content	mg/mL	Null	3.33	-6.00	13.98			adequate performance
		DSPC content	mg/mL	Null	5.30	-9.86	21.92			
		LNP Polydispersity	-	Null	5.09	-9.43	21.10			no Ppk
		LNP Size	nm	Null	3.25	-3.26	16.26			
		RNA content	mg/mL	Result >= M..	2.29	-5.06	8.65	0.70		low performance
		RNA Encapsulation	%	Null	2.17	-4.33	8.72			
	LNP_C-IPC3	RNA Integrity	%	Null	6.06	-11.70	24.64			no Ppk
		ALC-0159 content	mg/mL	Null	2.12	-1.92	10.83			
		ALC-0315 content	mg/mL	Null	2.59	-3.56	12.00			adequate performance
		Cholesterol content	mg/mL	Null	1.63	-2.15	7.61			
		DSPC content	mg/mL	Null	4.62	-7.82	19.91			no Ppk
		LNP Polydispersity	-	Null	4.30	-8.77	17.05			
		LNP Size	nm	Null	4.05	-7.04	17.27			adequate performance
		RNA content	mg/mL	Null	2.79	-4.27	12.44			
	TFF2_RE-IP..	RNA Encapsulation	%	Null	3.07	-5.04	13.41			no Ppk
		RNA Integrity	%	Null	3.91	-6.28	17.21			
		ALC-0159 content	mg/mL	Null	3.15	-3.50	15.37			adequate performance
		ALC-0315 content	mg/mL	Null	2.69	-2.81	13.33			
		Bacterial Endotoxin	EU/mL	Result <= M..	6.92	4.52	46.05		35.00	low performance
		Cholesterol content	mg/mL	Null	4.43	-8.24	18.36			
		DSPC content	mg/mL	Null	3.90	-5.48	17.90			no Ppk
		LNP Polydispersity	-	Null	5.09	-8.78	21.75			
		LNP Size	nm	Null	4.07	-6.42	18.02			adequate performance
		RNA content	mg/mL	Null	5.21	-8.97	22.27			
		RNA Encapsulation	%	Null	5.32	-9.98	21.95			no Ppk
		RNA Integrity	%	Null	3.09	-4.37	14.18			
		TAMC	CFU/10mL	Result <= M..	1.98	-0.01	11.87		10.00	low performance
		TYMC	CFU/10mL	Result <= M..	2.23	-1.42	11.99		10.00	