



Kit Quality Control Report

RPH CENTRAL PHARMA

CNPJ: 19.315.658/0001-10
 R: Maestro Cardim, 769 - São Paulo/SP
 Farm. RT: Priscila Larcher CRF/SP-74.417

Date: From 21/05/2021 To 21/05/2021

Product:	Manuf:	Calibration D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210521-024		21/05/2021 07:29	GS	Butanona Normal Saline	3MM Whatman Sílica gel	355 5,2		5 74,9	0		92,119 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210521-026		21/05/2021 07:40	GS	Butanona Normal Saline	3MM Whatman Sílica gel	149,4 9,8		0,8 124,5	0		92,17 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210521-027		21/05/2021 07:51	GS	Butanona Normal Saline	3MM Whatman Sílica gel	161,1 7,4		3,2 99,4	0		91,124 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210521-029		21/05/2021 08:03	GS	Butanona Normal Saline	3MM Whatman Sílica gel	193 9,7		2,3 141,4	0		92,403 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210521-032		21/05/2021 10:39	WG	Butanona Normal Saline	3MM Whatman Sílica gel	89,4 8,3		2,8 128,7	0		90,905 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DOTATATE-68Ga Lot # K-20210521-034		21/05/2021 12:41	JS	Citrato de Sódio 0,1M Metanol/Acetato de Amonio 1	Sílica gel Sílica gel	23,7 0,3		0,8 43,8	0		96,054 %	Pass
					Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DTPA-99mTc Lot # K-20210521-010	RPH	21/05/2021 04:03	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1248 75		20 961	0		91,183 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20210521-011	RPH	21/05/2021 04:06	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	479 13		12 531	0		95,166 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20210521-016	RPH	21/05/2021 04:14	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	1059 25		14 812	0		95,708 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20210521-031	RPH	21/05/2021 10:15	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	490 4		6 455	0		97,919 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
FITATO-99mTc Lot # K-20210521-006		21/05/2021 03:15	PP	Butanona	3MM Whatman	877		28	0		96,906 %	Pass
					Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 7,00

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
FITATO-99mTc Lot # K-20210521-023		21/05/2021 07:12	GS	Butanona		3MM Whatman		654		5	0	99,241 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
											Límpido/Incolor			
MAA-99mTc Lot # K-20210521-012		21/05/2021 04:07	PP	Butanona		3MM Whatman		440		23	0	95,032 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210521-013		21/05/2021 04:09	PP	Butanona		3MM Whatman		339		1	0	99,706 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210521-014		21/05/2021 04:11	PP	Butanona		3MM Whatman		482		1	0	99,793 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210521-015		21/05/2021 04:12	PP	Butanona		3MM Whatman		280		8	0	97,222 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210521-017		21/05/2021 04:37	PP	Butanona		3MM Whatman		367		9	0	97,606 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210521-018		21/05/2021 04:38	PP	Butanona		3MM Whatman		348		11	0	96,936 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210521-035		21/05/2021 13:36	WG	Butanona		3MM Whatman		340		12	0	96,591 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210521-004		21/05/2021 03:09	PP	Acetona		3MM Whatman		929		6	0	97,986 %	Pass	
				Normal Saline		3MM Whatman		8		575	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210521-005		21/05/2021 03:12	PP	Acetona		3MM Whatman		1120		40	0	96,185 %	Pass	
				Normal Saline		3MM Whatman		3		814	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210521-020		21/05/2021 06:55	GS	Acetona		3MM Whatman		339		1	0	95,803 %	Pass	
				Normal Saline		3MM Whatman		16		394	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210521-021		21/05/2021 06:58	GS	Acetona		3MM Whatman		439		1	0	99,645 %	Pass	
				Normal Saline		3MM Whatman		1		779	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210521-025		21/05/2021 07:29	GS	Acetona		3MM Whatman		980		4	0	99,49 %	Pass	
				Normal Saline		3MM Whatman		1		963	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			

Mo99 less than 0.15 uCi/mCi Tc99m. Alumina Ion Test Negative.

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Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
MDP-99mTc Lot # K-20210521-036		21/05/2021 13:54	WG	Acetona Normal Saline	3MM	Whatman		631 35		7 952	0	pH (Low/Actual/High)	95,357 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-001		21/05/2021 02:46	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		2075 1		3 3048	0	pH (Low/Actual/High)	99,823 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-002		21/05/2021 02:49	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		270 5		4 398	0	pH (Low/Actual/High)	97,299 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-003		21/05/2021 02:52	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		307 5		7 394	0	pH (Low/Actual/High)	96,518 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-007		21/05/2021 03:16	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		1921 1		34 299	0	pH (Low/Actual/High)	97,928 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-008		21/05/2021 03:39	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		3087 22		5 3040	0	pH (Low/Actual/High)	99,12 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-009		21/05/2021 03:51	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		343 12		7 4080	0	pH (Low/Actual/High)	97,707 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-019		21/05/2021 06:55	GS	Normal Saline Metanol	Sílica gel 3MM	Whatman		1092 20		15 1442	0	pH (Low/Actual/High)	97,277 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-022		21/05/2021 07:09	GS	Normal Saline Metanol	Sílica gel 3MM	Whatman		1149 20		34 1278	0	pH (Low/Actual/High)	95,585 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210521-028		21/05/2021 08:03	GS	Normal Saline Metanol	Sílica gel 3MM	Whatman		1060 25		12 1619	0	pH (Low/Actual/High)	97,36 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210521-030		21/05/2021 09:34	SB	Acetato de amônio 1M:Metanol	Sílica gel			0,3		34,9	0	pH (Low/Actual/High)	99,148 %	Pass 4,00 <= 4,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210521-001		21/05/2021 02:41	PP	Butanona	3MM	Whatman		8		1040	0	pH (Low/Actual/High)	99,237 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210521-002		21/05/2021 02:52	PP	Butanona	3MM	Whatman		3		1166	0	pH (Low/Actual/High)	99,743 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														

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Product:	Manuf:	Calibration D/T	Solution	Media	Origin	Middle	Top	Solution 2	Media 2	Origin 2	Top 2	% Tag	QC By	Pass Fail
Tecnécio-99m Lot # E-20210521-003		21/05/2021 02:53	PP	Butanona		3MM Whatman		4		172	0		97,727 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210521-004		21/05/2021 06:49	GS	Butanona		3MM Whatman		4		840	0		99,526 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210521-005		21/05/2021 07:27	GS	Butanona		3MM Whatman		4		1219	0		99,673 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210521-006		21/05/2021 08:48	JS	Butanona		3MM Whatman		1		2500	0		99,96 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
												Límpido e Incolor		
Tecnécio-99m Lot # E-20210521-009		21/05/2021 13:30	WG	Butanona		3MM Whatman		2		1234	0		99,838 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												Límpido e Incolor		

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