



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 27/05/2021 To 27/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210527-011	27/05/2021	04:03	PP		Butanona	3MM Whatman	192		3	0		92,491 %	Pass
					Normal Saline	Silica gel	8		126	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210527-018	27/05/2021	07:31	FS		Butanona	3MM Whatman	139,2		5,4	0		95,256 %	Pass
					Normal Saline	Silica gel	1,2		117,7	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DMSA-99mTc Lot # K-20210527-023	27/05/2021	08:07	GF		Butanona	3MM Whatman	71,2		0,5	0		93,161 %	Pass
					Normal Saline	Silica gel	4,6		70,3	pH (Low/Actual/High)	2,00 <= 3,00	<= 3,00	
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210527-036	27/05/2021	11:15	SB		Citrato de Sódio 0,1M	Silica gel	72,3		3	0		88,324 %	Fail
					Metanol/Acetato de Amonio 1	Silica gel	3,8		45,6	pH (Low/Actual/High)	4,00 <= 4,00	<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210527-015	27/05/2021	06:56	BB		Citrato de Sódio 0,1M	Silica gel	24,3		0,2	0		99,184 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210527-021	27/05/2021	07:55	JS		Citrato de Sódio 0,1M	Silica gel	45,9		0,4	0		99,136 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210527-037	27/05/2021	12:23	JS		Citrato de Sódio 0,1M	Silica gel	29,5		0,2	0		99,327 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00	
Límpido e Incolor													
DTPA-99mTc Lot # K-20210527-006	RPH	27/05/2021	03:30	PP	Acetona	3MM Whatman	1745		12	0		97,231 %	Pass
					Normal Saline	3MM Whatman	34		1596	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20210527-007	RPH	27/05/2021	03:32	PP	Acetona	3MM Whatman	928		5	0		97,401 %	Pass
					Normal Saline	3MM Whatman	15		712	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20210527-022	RPH	27/05/2021	08:04	GF	Acetona	3MM Whatman	271		3	0		95,88 %	Pass
					Normal Saline	3MM Whatman	17		545	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
Límpido/Incolor													
DTPA-99mTc Lot # K-20210527-029	RPH	27/05/2021	10:22	WG	Acetona	3MM Whatman	425		4	0		95,014 %	Pass
					Normal Saline	3MM Whatman	12		284	pH (Low/Actual/High)	3,80 <= 6,00	<= 7,50	
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
FITATO-99mTc Lot # K-20210527-009	27/05/2021	04:00	PP	Butanona	3MM	Whatman		633		12	0	98,14 %	Pass	
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210527-010	27/05/2021	04:03	PP	Butanona	3MM	Whatman		252		2	0	99,213 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210527-012	27/05/2021	04:04	PP	Butanona	3MM	Whatman		190		2	0	98,958 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210527-013	27/05/2021	04:06	PP	Butanona	3MM	Whatman		171		1	0	99,419 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210527-030	27/05/2021	10:24	WG	Butanona	3MM	Whatman		224		3	0	98,678 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210527-032	27/05/2021	10:28	WG	Butanona	3MM	Whatman		156,6		5	0	96,906 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210527-003	27/05/2021	02:50	PP	Acetona	3MM	Whatman		1443		22	0	97,455 %	Pass	
				Normal Saline	3MM	Whatman		17		1613		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210527-005	27/05/2021	02:52	PP	Acetona	3MM	Whatman		714		4	0	98,712 %	Pass	
				Normal Saline	3MM	Whatman		5		679		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210527-008	27/05/2021	03:59	PP	Acetona	3MM	Whatman		1100		1	0	97,947 %	Pass	
				Normal Saline	3MM	Whatman		26		1299		pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210527-017	27/05/2021	07:23	FS	Acetona	3MM	Whatman		590		1	0	97,606 %	Pass	
				Normal Saline	3MM	Whatman		18		791		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210527-019	27/05/2021	07:37	FS	Acetona	3MM	Whatman		610		2	0	95,988 %	Pass	
				Normal Saline	3MM	Whatman		67		1751		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210527-020	27/05/2021	07:47	GF	Acetona	3MM	Whatman		555		3	0	97,804 %	Pass	
				Normal Saline	3MM	Whatman		10		593		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MIBI-99mTc Lot # K-20210527-002	27/05/2021	02:41	PP	Normal Saline		Silica gel		2033		22	0	98,643 %	Pass	
				Metanol		3MM Whatman		6		2087		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
												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
MIBI-99mTc Lot # K-20210527-001	27/05/2021	02:42 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1548 4		28 2221	0	pH (Low/Actual/High)	98,044 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-004	27/05/2021	02:52 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2278 11		40 2944	0	pH (Low/Actual/High)	97,902 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-014	27/05/2021	06:49 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			536 3		8 866	0	pH (Low/Actual/High)	98,184 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-016	27/05/2021	07:13 FS	Normal Saline Metanol		Sílica gel 3MM Whatman			606 10		12 814	0	pH (Low/Actual/High)	96,845 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-025	27/05/2021	09:48 BB	Normal Saline Metanol		Sílica gel 3MM Whatman			774 4		9 500	0	pH (Low/Actual/High)	98,057 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-031	27/05/2021	10:31 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			744 2		8 992	0	pH (Low/Actual/High)	98,735 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-034	27/05/2021	10:35 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			462 4		3 734	0	pH (Low/Actual/High)	98,813 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210527-035	27/05/2021	11:14 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			360 7		3 452	0	pH (Low/Actual/High)	97,648 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210527-024	27/05/2021	09:36 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,1		33,5	0	pH (Low/Actual/High)	99,702 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210527-001	27/05/2021	02:34 PP	Butanona		3MM Whatman			4		1322	0	pH (Low/Actual/High)	99,698 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210527-002	27/05/2021	02:39 PP	Butanona		3MM Whatman			1		270	0	pH (Low/Actual/High)	99,631 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210527-003	27/05/2021	02:45 PP	Butanona		3MM Whatman			1		418	0	pH (Low/Actual/High)	99,761 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210527-004	27/05/2021	02:48 PP	Butanona		3MM Whatman			1		944	0	pH (Low/Actual/High)	99,894 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e 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
Tecnécio-99m Lot # E-20210527-005		27/05/2021 03:26 PP	Butanona		3MM	Whatman		13		2771	0		99,533 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-006		27/05/2021 03:41 PP	Butanona		3MM	Whatman		4		140	0		97,222 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-007		27/05/2021 03:52 PP	Butanona		3MM	Whatman		22		767	0		97,212 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-008		27/05/2021 03:54 PP	Butanona		3MM	Whatman		5		657	0		99,245 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-009		27/05/2021 03:55 PP	Butanona		3MM	Whatman		7		508	0		98,641 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-010		27/05/2021 03:55 PP	Butanona		3MM	Whatman		14		2964	0		99,53 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-011		27/05/2021 06:46 FS	Butanona		3MM	Whatman		8		1022	0		99,223 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-013		27/05/2021 06:58 FS	Butanona		3MM	Whatman		8		1196	0		99,336 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-014		27/05/2021 07:09 FS	Butanona		3MM	Whatman		8		582	0		98,644 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-015		27/05/2021 07:21 FS	Butanona		3MM	Whatman		6		361	0		98,365 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-016		27/05/2021 07:32 FS	Butanona		3MM	Whatman		8		345	0		97,734 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-017		27/05/2021 07:43 FS	Butanona		3MM	Whatman		8		645	0		98,775 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-019		27/05/2021 08:05 GF	Butanona		3MM	Whatman		11		309	0		96,563 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e 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
Tecnécio-99m Lot # E-20210527-021		27/05/2021 09:45	BB	Butanona		3MM Whatman		11		1562	0		99,301 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-022		27/05/2021 09:56	BB	Butanona		3MM Whatman		3		937	0		99,681 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-023		27/05/2021 10:20	BB	Butanona		3MM Whatman		1		531	0		99,812 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-024		27/05/2021 10:27	WG	Butanona		3MM Whatman		1,8		197,8	0		99,098 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210527-025		27/05/2021 11:11	WG	Butanona		3MM Whatman		7		1140	0		99,39 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m		27/05/2021 17:01												%
TRODAT-99mTc Lot # K-20210527-028		27/05/2021 10:13	WG	Normal Saline		Sílica gel		118,8		5	0		91,714 %	Pass
				Butanona		3MM Whatman		7		157,8		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210527-027		27/05/2021 10:14	WG	Normal Saline		Sílica gel		88,8		4	0		92,116 %	Pass
				Butanona		3MM Whatman		5,6		151,1		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210527-028		27/05/2021 10:15	WG	Normal Saline		Sílica gel		125		3,8	0		93,673 %	Pass
				Butanona		3MM Whatman		4,2		120,2		pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50
														Límpido/Incolor

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

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