



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 18/05/2021 To 18/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210518-018		18/05/2021	04:39	PP	Butanona Normal Saline	3MM Whatman Sílica gel	380 25		1 234	0		90,085 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210518-026		18/05/2021	07:25	GS	Butanona Normal Saline	3MM Whatman Sílica gel	1411 25		29 984	0		95,508 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DMSA-99mTc Lot # K-20210518-029		18/05/2021	08:00	GS	Butanona Normal Saline	3MM Whatman Sílica gel	1183 10		5 126	0		92,226 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		2,00 <= 3,00	<= 3,00
DOTATOC-68Ga Lot # K-20210518-040		18/05/2021	12:52	MP	Citrato de Sódio 0,1M	Sílica gel	49,5		0,4	0		99,198 %	Pass
						Límpido e Incolor				pH (Low/Actual/High)		4,00 <= 5,00	<= 8,00
DTPA-99mTc Lot # K-20210518-008	RPH	18/05/2021	03:31	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	912 11		1 1050	0		98,854 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
DTPA-99mTc Lot # K-20210518-027	RPH	18/05/2021	07:40	GS	Acetona Normal Saline	3MM Whatman 3MM Whatman	776 9		1 563	0		98,298 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 7,00	<= 7,50
DTPA-99mTc Lot # K-20210518-034	RPH	18/05/2021	10:38	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	916 16		1 732	0		97,752 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		3,80 <= 6,00	<= 7,50
FITATO-99mTc Lot # K-20210518-006		18/05/2021	03:30	PP	Butanona	3MM Whatman	416		4	0		99,048 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 6,00	<= 7,00
FITATO-99mTc Lot # K-20210518-037		18/05/2021	10:59	WG	Butanona	3MM Whatman	619		1	0		99,839 %	Pass
						Límpido/Incolor				pH (Low/Actual/High)		5,00 <= 7,00	<= 7,00
MAA-99mTc Lot # K-20210518-013		18/05/2021	04:11	PP	Butanona	3MM Whatman	333		11	0		96,802 %	Pass
						Turvo/Incolor				pH (Low/Actual/High)		3,00 <= 6,00	<= 6,00
MAA-99mTc Lot # K-20210518-012		18/05/2021	04:11	PP	Butanona	3MM Whatman	331		4	0		98,806 %	Pass
						Turvo/Incolor				pH (Low/Actual/High)		3,00 <= 6,00	<= 6,00

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
MAA-99mTc Lot # K-20210518-014		18/05/2021 04:14 PP	Butanona		3MM	Whatman		185		1	0	99,462 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-015		18/05/2021 04:15 PP	Butanona		3MM	Whatman		293		3	0	98,986 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-016		18/05/2021 04:16 PP	Butanona		3MM	Whatman		271		2	0	99,267 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-017		18/05/2021 04:40 PP	Butanona		3MM	Whatman		550		10	0	98,214 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-019		18/05/2021 04:41 PP	Butanona		3MM	Whatman		155		7	0	95,679 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-020		18/05/2021 04:42 PP	Butanona		3MM	Whatman		88		4,4	0	95,238 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-021		18/05/2021 04:44 PP	Butanona		3MM	Whatman		413		2	0	99,518 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-035		18/05/2021 10:42 WG	Butanona		3MM	Whatman		125,1		6,5	0	95,061 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-036		18/05/2021 10:46 WG	Butanona		3MM	Whatman		404		4	0	99,02 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-038		18/05/2021 11:01 WG	Butanona		3MM	Whatman		283		3	0	98,951 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210518-039		18/05/2021 11:05 WG	Butanona		3MM	Whatman		366		9	0	97,60 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210518-004		18/05/2021 02:56 PP	Acetona		3MM	Whatman		285		3	0	98,859 %	Pass	
			Normal Saline		3MM	Whatman		2		2015	pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210518-009		18/05/2021 03:36 PP	Acetona		3MM	Whatman		2061		7	0	97,066 %	Pass	
			Normal Saline		3MM	Whatman		64		2402	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-20210518-011		18/05/2021 03:52 PP	Acetona Normal Saline		3MM Whatman 3MM Whatman			3094 18		55 2692	0	pH (Low/Actual/High)	97,589 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210518-025		18/05/2021 07:25 GS	Acetona Normal Saline		3MM Whatman 3MM Whatman			705 3		4 960	0	pH (Low/Actual/High)	99,124 %	Pass 4,00 <= 7,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210518-028		18/05/2021 07:49 GS	Acetona Normal Saline		3MM Whatman 3MM Whatman			872 1		2 442	0	pH (Low/Actual/High)	99,545 %	Pass 4,00 <= 7,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-001		18/05/2021 02:15 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			246 3		3 416	0	pH (Low/Actual/High)	98,079 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-002		18/05/2021 02:20 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1498 13		29 391	0	pH (Low/Actual/High)	94,883 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-003		18/05/2021 02:23 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			310 1		7 315	0	pH (Low/Actual/High)	97,475 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-005		18/05/2021 03:27 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			2067 2		5 2028	0	pH (Low/Actual/High)	99,66 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-007		18/05/2021 03:32 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3020 24		7 3081	0	pH (Low/Actual/High)	98,996 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-010		18/05/2021 03:51 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			3095 41		21 3844	0	pH (Low/Actual/High)	98,271 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-022		18/05/2021 07:02 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			1491 12		18 1421	0	pH (Low/Actual/High)	97,97 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-023		18/05/2021 07:03 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			857 13		9 1361	0	pH (Low/Actual/High)	98,015 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-024		18/05/2021 07:08 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			1574 21		26 1406	0	pH (Low/Actual/High)	96,903 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210518-030		18/05/2021 09:10 GS	Normal Saline Metanol		Sílica gel 3MM Whatman			458 5		1 431	0	pH (Low/Actual/High)	98,635 %	Pass 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
PSMA-68Ga Lot # K-20210518-031		18/05/2021 09:34	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,3		48,8	0		99,389 %	Pass
												pH (Low/Actual/High)	4,00 <= 5,00	<= 8,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-001		18/05/2021 02:13	PP	Butanona		3MM Whatman		1		715	0		99,86 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-002		18/05/2021 02:16	PP	Butanona		3MM Whatman		1		625	0		99,84 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-003		18/05/2021 02:20	PP	Butanona		3MM Whatman		6		583	0		98,981 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-004		18/05/2021 03:22	PP	Butanona		3MM Whatman		6		575	0		98,967 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-005		18/05/2021 03:28	PP	Butanona		3MM Whatman		5		735	0		99,324 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-006		18/05/2021 03:48	PP	Butanona		3MM Whatman		10		1086	0		99,088 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-007		18/05/2021 03:49	PP	Butanona		3MM Whatman		11		948	0		98,853 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-008		18/05/2021 04:37	PP	Butanona		3MM Whatman		33		1918	0		98,309 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-009		18/05/2021 06:58	GS	Butanona		3MM Whatman		2		325	0		99,388 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-010		18/05/2021 06:59	GS	Butanona		3MM Whatman		1		199	0		99,50 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-011		18/05/2021 07:06	GS	Butanona		3MM Whatman		18		1477	0		98,796 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-012		18/05/2021 07:22	GS	Butanona		3MM Whatman		5		768	0		99,353 %	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-20210518-013	18/05/2021	07:22	GS	Butanona	3MM	Whatman		31		825	0	96,379 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-014	18/05/2021	07:46	GS	Butanona	3MM	Whatman		18		870	0	97,973 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-015	18/05/2021	07:59	GS	Butanona	3MM	Whatman		6		326	0	98,193 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-016	18/05/2021	09:01	JS	Butanona	3MM	Whatman		1		857	0	99,883 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-018	18/05/2021	10:22	GS	Butanona	3MM	Whatman		5		257	0	98,092 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-019	18/05/2021	10:35	JS	Butanona	3MM	Whatman		1		571	0	99,825 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210518-020	18/05/2021	10:45	WG	Butanona	3MM	Whatman		39		1470	0	97,416 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
TRODAT-99mTc Lot # K-20210518-032	18/05/2021	10:31	WG	Normal Saline	Sílica gel			162,4		4,3	0	95,971 %	Pass	
				Butanona	3MM	Whatman		3		204	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor
TRODAT-99mTc Lot # K-20210518-033	18/05/2021	10:32	WG	Normal Saline	Sílica gel			66,3		2,1	0	95,659 %	Pass	
				Butanona	3MM	Whatman		2,5		194,2	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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