



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 25/05/2021 To 25/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210525-028		25/05/2021	08:13	JS	Butanona	3MM Whatman	240		1	0		95,01 %	Pass
					Normal Saline	Silica gel	7		146	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DMSA-99mTc Lot # K-20210525-036		25/05/2021	10:28	WG	Butanona	3MM Whatman	75,9		4	0		90,734 %	Pass
					Normal Saline	Silica gel	4		89,9	pH (Low/Actual/High)	2,00 <= 3,00 <= 3,00		
Límpido/Incolor													
DOTATATE-68Ga Lot # K-20210525-027		25/05/2021	07:52	GF	Citrato de Sódio 0,1M	Silica gel	42		0,6	0		92,117 %	Pass
					Metanol/Acetato de Amonio 1	Silica gel	0,9		13	pH (Low/Actual/High)	4,00 <= 4,50 <= 8,00		
Límpido e Incolor													
DOTATATE-68Ga Lot # K-20210525-038		25/05/2021	15:16	SB	Citrato de Sódio 0,1M	Silica gel	11,83		25,5	0		0,00 %	Fail
					Metanol/Acetato de Amonio 1	Silica gel	23,1		0	pH (Low/Actual/High)	4,00 <= 4,00 <= 8,00		
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210525-019		25/05/2021	06:54	GF	Citrato de Sódio 0,1M	Silica gel	9,63		0,35	0		96,493 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20210525-037		25/05/2021	13:00	JS	Citrato de Sódio 0,1M	Silica gel	45,9		0,3	0		99,351 %	Pass
										pH (Low/Actual/High)	4,00 <= 5,00 <= 8,00		
Límpido e Incolor													
DTPA-99mTc Lot # K-20210525-013	RPH	25/05/2021	04:04	PP	Acetona	3MM Whatman	805		1	0		96,57 %	Pass
					Normal Saline	3MM Whatman	16		468	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
DTPA-99mTc Lot # K-20210525-014	RPH	25/05/2021	04:05	PP	Acetona	3MM Whatman	714		4	0		95,50 %	Pass
					Normal Saline	3MM Whatman	22		536	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
DTPA-99mTc Lot # K-20210525-024	RPH	25/05/2021	07:22	GF	Acetona	3MM Whatman	1322		21	0		95,984 %	Pass
					Normal Saline	3MM Whatman	26		1034	pH (Low/Actual/High)	3,80 <= 5,00 <= 7,50		
Límpido/Incolor													
DTPA-99mTc Lot # K-20210525-031	RPH	25/05/2021	09:46	WG	Acetona	3MM Whatman	93,8		1,6	0		94,06 %	Pass
					Normal Saline	3MM Whatman	5		112,3	pH (Low/Actual/High)	3,80 <= 6,00 <= 7,50		
Límpido/Incolor													
FITATO-99mTc Lot # K-20210525-010		25/05/2021	03:11	PP	Butanona	3MM Whatman	505		3	0		99,409 %	Pass
										pH (Low/Actual/High)	5,00 <= 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-20210525-034		25/05/2021 10:17	WG	Butanona		3MM Whatman		542		2	0	99,632 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00	
											Límpido/Incolor			
MAA-99mTc Lot # K-20210525-006		25/05/2021 03:03	PP	Butanona		3MM Whatman		375		16	0	95,908 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-007		25/05/2021 03:05	PP	Butanona		3MM Whatman		176		3	0	98,324 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-008		25/05/2021 03:06	PP	Butanona		3MM Whatman		467		46	0	91,033 %	Fail	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-009		25/05/2021 03:07	PP	Butanona		3MM Whatman		236		3	0	98,745 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-015		25/05/2021 04:09	PP	Butanona		3MM Whatman		425		3	0	99,299 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-016		25/05/2021 04:09	PP	Butanona		3MM Whatman		329		13	0	96,199 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-018		25/05/2021 04:47	PP	Butanona		3MM Whatman		698		8	0	98,867 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-017		25/05/2021 04:47	PP	Butanona		3MM Whatman		305		6	0	98,071 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MAA-99mTc Lot # K-20210525-032		25/05/2021 09:51	WG	Butanona		3MM Whatman		379		6	0	98,442 %	Pass	
											pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
											Turvo/Incolor			
MDP-99mTc Lot # K-20210525-003		25/05/2021 02:53	PP	Acetona		3MM Whatman		1051		17	0	95,483 %	Pass	
				Normal Saline		3MM Whatman		21		697	pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210525-011		25/05/2021 03:26	PP	Acetona		3MM Whatman		820		56	0	90,889 %	Pass	
				Normal Saline		3MM Whatman		14		501	pH (Low/Actual/High)	4,00 <= 7,00	<= 7,80	
											Límpido/Incolor			
MDP-99mTc Lot # K-20210525-022		25/05/2021 07:10	GF	Acetona		3MM Whatman		622		1	0	99,052 %	Pass	
				Normal Saline		3MM Whatman		4		504	pH (Low/Actual/High)	4,00 <= 5,00	<= 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-20210525-026	25/05/2021	07:48	GF	Acetona Normal Saline	3MM	Whatman		677 10		0 687	0	pH (Low/Actual/High)	98,565 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-001	25/05/2021	01:31	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		3365 86		99 4057	0	pH (Low/Actual/High)	95,066 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-002	25/05/2021	02:15	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		2802 72		5 3710	0	pH (Low/Actual/High)	97,918 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-004	25/05/2021	02:57	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		1380 30		26 2054	0	pH (Low/Actual/High)	96,711 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-005	25/05/2021	03:02	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		1547 32		30 2398	0	pH (Low/Actual/High)	96,781 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-012	25/05/2021	03:33	PP	Normal Saline Metanol	Sílica gel 3MM	Whatman		1976 75		23 1905	0	pH (Low/Actual/High)	95,062 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-020	25/05/2021	07:04	GF	Normal Saline Metanol	Sílica gel 3MM	Whatman		883 16		16 1238	0	pH (Low/Actual/High)	96,944 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-021	25/05/2021	07:08	GF	Normal Saline Metanol	Sílica gel 3MM	Whatman		600 1		5 1250	0	pH (Low/Actual/High)	99,094 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-025	25/05/2021	07:46	GF	Normal Saline Metanol	Sílica gel 3MM	Whatman		887 4		15 1155	0	pH (Low/Actual/High)	97,992 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-029	25/05/2021	09:26	JS	Normal Saline Metanol	Sílica gel 3MM	Whatman		1217 5		22 1743	0	pH (Low/Actual/High)	97,938 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210525-030	25/05/2021	09:35	WG	Normal Saline Metanol	Sílica gel 3MM	Whatman		1847 2		11 1316	0	pH (Low/Actual/High)	99,256 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210525-023	25/05/2021	07:14	GF	Butanona Normal Saline	3MM	Whatman		307 0		1 249	0	pH (Low/Actual/High)	99,675 %	Pass 5,00 <= 5,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210525-033	25/05/2021	10:05	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,4		34,6	0	pH (Low/Actual/High)	98,857 %	Pass 4,00 <= 6,00 <= 8,00
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-20210525-001		25/05/2021 01:26 PP	Butanona		3MM	Whatman		8		604	0		98,693 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-002		25/05/2021 02:11 PP	Butanona		3MM	Whatman		2		4609	0		99,957 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-003		25/05/2021 02:54 PP	Butanona		3MM	Whatman		22		571	0		96,29 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-004		25/05/2021 02:59 PP	Butanona		3MM	Whatman		1		5058	0		99,98 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-005		25/05/2021 03:31 PP	Butanona		3MM	Whatman		36		2287	0		98,45 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-007		25/05/2021 06:57 GF	Butanona		3MM	Whatman		0		258	0		100,00 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-008		25/05/2021 07:06 GF	Butanona		3MM	Whatman		2		211	0		99,061 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-009		25/05/2021 07:11 GF	Butanona		3MM	Whatman		1		323	0		99,691 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-010		25/05/2021 07:42 GF	Butanona		3MM	Whatman		4		252	0		98,438 %	Pass
												pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-012		25/05/2021 09:23 WG	Butanona		3MM	Whatman		3		1928	0		99,845 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-013		25/05/2021 09:33 JS	Butanona		3MM	Whatman		1		3450	0		99,971 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-014		25/05/2021 09:42 WG	Butanona		3MM	Whatman		120		2960	0		96,104 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
														Límpido e Incolor
Tecnécio-99m Lot # E-20210525-016		25/05/2021 12:29 JS	Butanona		3MM	Whatman		5		2550	0		99,804 %	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
TRODAT-99mTc		25/05/2021 10:21	WG	Normal Saline	Silica gel			84,4		4	0		92,618 %	Pass
Lot # K-20210525-035				Butanona	3MM Whatman			2,2		74,8	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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