



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 26/07/2021 To 26/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210726-029		26/07/2021	07:36	WG	Butanona Normal Saline	3MM Whatman Sílica gel	208 0,9		5 134,8	0	pH (Low/Actual/High)	96,989 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210726-030		26/07/2021	07:38	WG	Butanona Normal Saline	3MM Whatman Sílica gel	145 3		6 102,7	0	pH (Low/Actual/High)	93,188 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210726-034		26/07/2021	08:02	WG	Butanona Normal Saline	3MM Whatman Sílica gel	274 11		13 257	0	pH (Low/Actual/High)	91,366 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210726-040		26/07/2021	10:36	WG	Butanona Normal Saline	3MM Whatman Sílica gel	152,3 8		0,6 168,2	0	pH (Low/Actual/High)	95,067 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210726-041		26/07/2021	11:01	WG	Butanona Normal Saline	3MM Whatman Sílica gel	219 0,4		7 158,1	0	pH (Low/Actual/High)	96,65 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210726-038		26/07/2021	10:01	BB	Citrato de Sódio 0,1M	Sílica gel	30,3		0,4	0	pH (Low/Actual/High)	98,697 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210726-045		26/07/2021	16:02	JS	Citrato de Sódio 0,1M	Sílica gel	32,6		0,4	0	pH (Low/Actual/High)	98,788 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210726-015	RPH	26/07/2021	03:59	FN	Acetona Normal Saline	3MM Whatman 3MM Whatman	379 5		12 413	0	pH (Low/Actual/High)	95,735 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210726-028	RPH	26/07/2021	07:32	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	906 4		3 434	0	pH (Low/Actual/High)	98,757 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210726-039	RPH	26/07/2021	10:31	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	316 17		5 265	0	pH (Low/Actual/High)	92,414 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210726-017		26/07/2021	04:04	FN	Butanona	3MM Whatman	223		3	0	pH (Low/Actual/High)	98,673 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							

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-20210726-031		26/07/2021 07:50	WG	Butanona		3MM Whatman		226		1	0		99,559 %	Pass
												pH (Low/Actual/High)	5,00 <= 6,00	<= 7,00
												Límpido/Incolor		
MAA-99mTc Lot # K-20210726-011		26/07/2021 03:49	FN	Butanona		3MM Whatman		222		1	0		99,552 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-012		26/07/2021 03:51	FN	Butanona		3MM Whatman		117,1		1,3	0		98,902 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-013		26/07/2021 03:54	FN	Butanona		3MM Whatman		170,1		1,2	0		99,299 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-014		26/07/2021 03:56	FN	Butanona		3MM Whatman		201		2	0		99,015 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-018		26/07/2021 04:13	FN	Butanona		3MM Whatman		229		3	0		98,707 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-019		26/07/2021 04:15	FN	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-20210726-032		26/07/2021 07:56	WG	Butanona		3MM Whatman		290		1	0		99,656 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-033		26/07/2021 08:00	WG	Butanona		3MM Whatman		51,2		0,1	0		99,805 %	Pass
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210726-042		26/07/2021 12:46	JS	Butanona		3MM Whatman		85,6		2	0		97,717 %	Pass
												pH (Low/Actual/High)	3,00 <= 5,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210726-009		26/07/2021 03:45	FN	Acetona		3MM Whatman		1391		20	0		98,359 %	Pass
				Normal Saline		3MM Whatman		2		891		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210726-010		26/07/2021 03:45	FN	Acetona		3MM Whatman		730		10	0		98,124 %	Pass
				Normal Saline		3MM Whatman		5		948		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210726-020		26/07/2021 04:19	FN	Acetona		3MM Whatman		1143		6	0		98,403 %	Pass
				Normal Saline		3MM Whatman		6		552		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		

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-20210726-021		26/07/2021 04:20 FN	Acetona Normal Saline		3MM Whatman 3MM Whatman			1002 5		3 1032	0	pH (Low/Actual/High)	99,219 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210726-027		26/07/2021 07:27 WG	Acetona Normal Saline		3MM Whatman 3MM Whatman			1160 34		15 1447	0	pH (Low/Actual/High)	96,428 %	Pass 4,00 <= 7,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210726-037		26/07/2021 09:48 WG	Acetona Normal Saline		3MM Whatman 3MM Whatman			1037 23		9 1045	0	pH (Low/Actual/High)	96,986 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20210726-044		26/07/2021 13:08 JS	Acetona Normal Saline		3MM Whatman 3MM Whatman			549 9		1 484	0	pH (Low/Actual/High)	97,993 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-001		26/07/2021 02:11 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			684 12		6 914	0	pH (Low/Actual/High)	97,835 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-002		26/07/2021 02:12 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			229 1		7 200	0	pH (Low/Actual/High)	96,536 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-003		26/07/2021 02:18 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1180 2		20 816	0	pH (Low/Actual/High)	98,089 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-004		26/07/2021 02:19 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			717 5		20 708	0	pH (Low/Actual/High)	96,585 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-005		26/07/2021 03:07 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1068 2		20 224	0	pH (Low/Actual/High)	97,277 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-006		26/07/2021 03:08 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1279 12		20 1405	0	pH (Low/Actual/High)	97,613 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-007		26/07/2021 03:09 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1666 12		20 1614	0	pH (Low/Actual/High)	98,076 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-008		26/07/2021 03:13 FN	Normal Saline Metanol		Sílica gel 3MM Whatman			1416 4		20 307	0	pH (Low/Actual/High)	97,321 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-022		26/07/2021 06:09 WG	Normal Saline Metanol		Sílica gel 3MM Whatman			1739 21		6 2626	0	pH (Low/Actual/High)	98,863 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														

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-20210726-025	26/07/2021	07:05	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1030 8		27 2719	0	pH (Low/Actual/High)	97,152 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-026	26/07/2021	07:06	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1491 2		12 1671	0	pH (Low/Actual/High)	99,082 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-035	26/07/2021	08:56	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1110 13		9 2550	0	pH (Low/Actual/High)	98,688 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210726-036	26/07/2021	09:45	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			765 2		9 894	0	pH (Low/Actual/High)	98,614 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210726-016	26/07/2021	04:02	FN	Butanona Normal Saline	3MM Whatman 3MM Whatman			253 5		2 158,1	0	pH (Low/Actual/High)	96,15 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210726-023	26/07/2021	06:49	WG	Acetato de amônio 1M:Metanol	Sílica gel			0,3		24,8	0	pH (Low/Actual/High)	98,805 %	Pass 4,00 <= 7,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210726-043	26/07/2021	12:53	JS	Acetato de amônio 1M:Metanol	Sílica gel			0,2		36,5	0	pH (Low/Actual/High)	99,455 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210726-001	26/07/2021	02:07	GS	Butanona	3MM Whatman			10		811	0	pH (Low/Actual/High)	98,782 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210726-002	26/07/2021	02:15	FN	Butanona	3MM Whatman			2		428	0	pH (Low/Actual/High)	99,535 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210726-003	26/07/2021	03:01	FN	Butanona	3MM Whatman			2		335	0	pH (Low/Actual/High)	99,407 %	Pass 5,00 <= 5,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210726-004	26/07/2021	03:11	FN	Butanona	3MM Whatman			2		536	0	pH (Low/Actual/High)	99,628 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210726-005	26/07/2021	04:16	FN	Butanona	3MM Whatman			1		540	0	pH (Low/Actual/High)	99,815 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210726-007	26/07/2021	07:01	WG	Butanona	3MM Whatman			11		1525	0	pH (Low/Actual/High)	99,284 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														

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-20210726-008		26/07/2021 07:25	WG	Butanona		3MM	Whatman	34		3728	0		99,096 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210726-009		26/07/2021 07:30	WG	Butanona		3MM	Whatman	6		2028	0		99,705 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210726-010		26/07/2021 09:42	WG	Butanona		3MM	Whatman	12		1429	0		99,167 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210726-012		26/07/2021 10:59	WG	Butanona		3MM	Whatman	4		629	0		99,368 %	Pass
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210726-013		26/07/2021 12:44	PL	Butanona		3MM	Whatman	2		485	0		99,589 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20210726-016		26/07/2021 17:07	JS	Butanona		3MM	Whatman	4		188	0		97,917 %	Pass
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor