



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 31/05/2021 To 31/05/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210531-026		31/05/2021	07:42	JS	Butanona Normal Saline	3MM Whatman Sílica gel	204 5		3 82,8	0 pH (Low/Actual/High)		92,856 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210531-031		31/05/2021	10:21	WG	Butanona Normal Saline	3MM Whatman Sílica gel	272 9,8		7 137,7	0 pH (Low/Actual/High)		90,847 %	Pass <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATOC-68Ga Lot # K-20210531-029		31/05/2021	09:47	JS	Citrato de Sódio 0,1M	Sílica gel	23,9		0,5	0 pH (Low/Actual/High)		97,951 %	Pass <= 5,00 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210531-032		31/05/2021	10:48	JS	Citrato de Sódio 0,1M	Sílica gel	23,8		0,5	0 pH (Low/Actual/High)		97,942 %	Pass <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210531-011	RPH	31/05/2021	03:42	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	983 51		1 1463	0 pH (Low/Actual/High)		96,53 %	Pass <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210531-033	RPH	31/05/2021	10:54	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	462 11		2 415	0 pH (Low/Actual/High)		96,987 %	Pass <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210531-012		31/05/2021	03:45	PP	Butanona	3MM Whatman	211		4	0 pH (Low/Actual/High)		98,14 %	Pass <= 6,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210531-028		31/05/2021	07:50	JS	Butanona	3MM Whatman	476		3	0 pH (Low/Actual/High)		99,374 %	Pass <= 7,00 <= 7,00
						Límpido/Incolor							
MAA-99mTc Lot # K-20210531-014		31/05/2021	03:50	PP	Butanona	3MM Whatman	1088		5	0 pH (Low/Actual/High)		99,543 %	Pass <= 6,00 <= 6,00
						Turvo/Incolor							
MAA-99mTc Lot # K-20210531-015		31/05/2021	03:52	PP	Butanona	3MM Whatman	485		5	0 pH (Low/Actual/High)		98,98 %	Pass <= 6,00 <= 6,00
						Turvo/Incolor							
MAA-99mTc Lot # K-20210531-016		31/05/2021	03:55	PP	Butanona	3MM Whatman	480		9	0 pH (Low/Actual/High)		98,16 %	Pass <= 6,00 <= 6,00
						Turvo/Incolor							

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-20210531-017		31/05/2021 03:57 PP	Butanona		3MM	Whatman		219		2	0		99,095 %	Pass
							Turvo/Incolor					pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
MDP-99mTc Lot # K-20210531-007		31/05/2021 03:36 PP	Acetona		3MM	Whatman		1906		2	0		98,602 %	Pass
			Normal Saline		3MM	Whatman		16		1221		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-008		31/05/2021 03:37 PP	Acetona		3MM	Whatman		361		11	0		96,979 %	Pass
			Normal Saline		3MM	Whatman		1		1570		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-009		31/05/2021 03:38 PP	Acetona		3MM	Whatman		185		4	0		95,852 %	Pass
			Normal Saline		3MM	Whatman		33		1591		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-010		31/05/2021 03:39 PP	Acetona		3MM	Whatman		1184		7	0		95,626 %	Pass
			Normal Saline		3MM	Whatman		41		1042		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-022		31/05/2021 07:24 JS	Acetona		3MM	Whatman		423		1	0		99,318 %	Pass
			Normal Saline		3MM	Whatman		3		670		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-023		31/05/2021 07:32 JS	Acetona		3MM	Whatman		534		16	0		96,306 %	Pass
			Normal Saline		3MM	Whatman		11		1390		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-024		31/05/2021 07:34 JS	Acetona		3MM	Whatman		875		3	0		99,293 %	Pass
			Normal Saline		3MM	Whatman		5		1365		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-025		31/05/2021 07:36 JS	Acetona		3MM	Whatman		691		1	0		99,283 %	Pass
			Normal Saline		3MM	Whatman		5		869		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MDP-99mTc Lot # K-20210531-030		31/05/2021 10:19 JS	Acetona		3MM	Whatman		891		3	0		99,298 %	Pass
			Normal Saline		3MM	Whatman		5		1358		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210531-001		31/05/2021 02:16 PP	Normal Saline		Sílica gel			1595		3	0		99,465 %	Pass
			Metanol		3MM	Whatman		1		287		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210531-002		31/05/2021 02:20 PP	Normal Saline		Sílica gel			266		2	0		98,267 %	Pass
			Metanol		3MM	Whatman		3		301		pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00
							Límpido/Incolor							
MIBI-99mTc Lot # K-20210531-003		31/05/2021 02:26 PP	Normal Saline		Sílica gel			219		5	0		97,101 %	Pass
			Metanol		3MM	Whatman		2		298		pH (Low/Actual/High)	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-20210531-004		31/05/2021 02:31 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			1334 5		16 283	0	pH (Low/Actual/High)	97,079 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210531-005		31/05/2021 02:52 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			247 6		4 379	0	pH (Low/Actual/High)	96,848 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210531-006		31/05/2021 02:53 PP	Normal Saline Metanol		Sílica gel 3MM Whatman			264 4		5 434	0	pH (Low/Actual/High)	97,228 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210531-018		31/05/2021 06:34 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			640 8		13 994	0	pH (Low/Actual/High)	97,211 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210531-019		31/05/2021 06:35 GF	Normal Saline Metanol		Sílica gel 3MM Whatman			935 6		12 1212	0	pH (Low/Actual/High)	98,24 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210531-027		31/05/2021 07:47 JS	Normal Saline Metanol		Sílica gel 3MM Whatman			1711 11		23 1360	0	pH (Low/Actual/High)	97,871 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210531-013		31/05/2021 03:48 PP	Butanona Normal Saline		3MM Whatman 3MM Whatman			901 34		3 1245	0	pH (Low/Actual/High)	97,01 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210531-021		31/05/2021 07:24 JS	Butanona Normal Saline		3MM Whatman 3MM Whatman			405 5		1 423	0	pH (Low/Actual/High)	98,585 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210531-020		31/05/2021 06:39 BB	Acetato de amônio 1M:Metanol		Sílica gel			0,4		36,2	0	pH (Low/Actual/High)	98,907 %	Pass 4,00 <= 4,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210531-034		31/05/2021 12:42 SB	Acetato de amônio 1M:Metanol		Sílica gel			0,2		37	0	pH (Low/Actual/High)	99,462 %	Pass 4,00 <= 4,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210531-001		31/05/2021 02:13 PP	Butanona		3MM Whatman			4		832	0	pH (Low/Actual/High)	99,522 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210531-002		31/05/2021 02:23 PP	Butanona		3MM Whatman			8		396	0	pH (Low/Actual/High)	98,02 %	Pass 5,00 <= 6,00 <= 6,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20210531-003		31/05/2021 02:49 PP	Butanona		3MM Whatman			4		587	0	pH (Low/Actual/High)	99,323 %	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-20210531-004		31/05/2021 03:22	PP	Butanona		3MM Whatman		16		844	0	98,14 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-005		31/05/2021 03:29	PP	Butanona		3MM Whatman		12		1478	0	99,195 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-006		31/05/2021 03:40	PP	Butanona		3MM Whatman		12		856	0	98,618 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-007		31/05/2021 06:29	GF	Butanona		3MM Whatman		1		908	0	99,89 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-009		31/05/2021 07:21	JS	Butanona		3MM Whatman		13		1940	0	99,334 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-010		31/05/2021 07:39	JS	Butanona		3MM Whatman		4		313	0	98,738 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-011		31/05/2021 07:44	JS	Butanona		3MM Whatman		4		343	0	98,847 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-013		31/05/2021 10:16	WG	Butanona		3MM Whatman		4		3823	0	99,895 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
Tecnécio-99m Lot # E-20210531-015		31/05/2021 12:21	SB	Butanona		3MM Whatman		30		2155	0	98,627 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	