



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 05/07/2021 To 05/07/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20210705-032		05/07/2021	08:02	BB	Butanona Normal Saline	3MM Whatman Sílica gel	106 6		4 174	0	pH (Low/Actual/High)	93,03 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210705-033		05/07/2021	08:03	GF	Butanona Normal Saline	3MM Whatman Sílica gel	81 6		1 82	0	pH (Low/Actual/High)	91,962 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210705-047		05/07/2021	11:06	WG	Butanona Normal Saline	3MM Whatman Sílica gel	151,8 3,7		2,2 88,9	0	pH (Low/Actual/High)	94,576 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DMSA-99mTc Lot # K-20210705-048		05/07/2021	11:09	WG	Butanona Normal Saline	3MM Whatman Sílica gel	227 4,4		2 70,8	0	pH (Low/Actual/High)	93,276 %	Pass 2,00 <= 3,00 <= 3,00
						Límpido/Incolor							
DOTATATE-68Ga Lot # K-20210705-036		05/07/2021	09:40	MP	Citrato de Sódio 0,1M Metanol/Acetato de Amonio 1	Sílica gel Sílica gel	33 0,9		0,3 44,2	0	pH (Low/Actual/High)	97,104 %	Pass 4,00 <= 4,50 <= 8,00
						Límpido e Incolor							
DOTATOC-68Ga Lot # K-20210705-037		05/07/2021	09:54	MP	Citrato de Sódio 0,1M	Sílica gel	33		0,2	0	pH (Low/Actual/High)	99,398 %	Pass 4,00 <= 5,00 <= 8,00
						Límpido e Incolor							
DTPA-99mTc Lot # K-20210705-008	RPH	05/07/2021	03:11	PP	Acetona Normal Saline	3MM Whatman 3MM Whatman	407 15		3 576	0	pH (Low/Actual/High)	96,73 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
DTPA-99mTc Lot # K-20210705-042	RPH	05/07/2021	10:31	WG	Acetona Normal Saline	3MM Whatman 3MM Whatman	560 6		9 635	0	pH (Low/Actual/High)	97,482 %	Pass 3,80 <= 6,00 <= 7,50
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210705-009		05/07/2021	03:27	PP	Butanona	3MM Whatman	565		11	0	pH (Low/Actual/High)	98,09 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							
FITATO-99mTc Lot # K-20210705-027		05/07/2021	07:13	GF	Butanona	3MM Whatman	210		2	0	pH (Low/Actual/High)	99,057 %	Pass 5,00 <= 6,00 <= 7,00
						Límpido/Incolor							
MAA-99mTc Lot # K-20210705-011		05/07/2021	03:53	PP	Butanona	3MM Whatman	166		6	0	pH (Low/Actual/High)	96,512 %	Pass 3,00 <= 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-20210705-012		05/07/2021	03:56	PP	Butanona		3MM	Whatman	131		3	0	97,761 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-013		05/07/2021	03:57	PP	Butanona		3MM	Whatman	206		1	0	99,517 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-014		05/07/2021	03:59	PP	Butanona		3MM	Whatman	87		2	0	97,753 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-015		05/07/2021	04:00	PP	Butanona		3MM	Whatman	186		6	0	96,875 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-018		05/07/2021	04:16	PP	Butanona		3MM	Whatman	199		4	0	98,03 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-019		05/07/2021	04:18	PP	Butanona		3MM	Whatman	33		1	0	97,059 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-020		05/07/2021	04:20	PP	Butanona		3MM	Whatman	70		1	0	98,592 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-021		05/07/2021	04:23	PP	Butanona		3MM	Whatman	86		3	0	96,629 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-034		05/07/2021	08:05	PP	Butanona		3MM	Whatman	324		3	0	99,083 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-035		05/07/2021	08:09	PP	Butanona		3MM	Whatman	348		3	0	99,145 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-043		05/07/2021	10:42	WG	Butanona		3MM	Whatman	122,8		1	0	99,192 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-044		05/07/2021	10:44	WG	Butanona		3MM	Whatman	304		5	0	98,382 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	
MAA-99mTc Lot # K-20210705-045		05/07/2021	10:47	WG	Butanona		3MM	Whatman	156,6		0,9	0	99,429 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00	

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-20210705-046		05/07/2021 11:03	WG	Butanona		3MM Whatman		99,6		0,8	0	99,203 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210705-049		05/07/2021 11:12	WG	Butanona		3MM Whatman		68		3,3	0	95,372 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210705-050		05/07/2021 11:14	WG	Butanona		3MM Whatman		278		5	0	98,233 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210705-051		05/07/2021 11:16	WG	Butanona		3MM Whatman		376		15	0	96,164 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MAA-99mTc Lot # K-20210705-052		05/07/2021 11:32	WG	Butanona		3MM Whatman		257		3	0	98,846 %	Pass	
												pH (Low/Actual/High)	3,00 <= 6,00	<= 6,00
												Turvo/Incolor		
MDP-99mTc Lot # K-20210705-006		05/07/2021 03:04	PP	Acetona		3MM Whatman		1092		2	0	98,969 %	Pass	
				Normal Saline		3MM Whatman		7		818		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-007		05/07/2021 03:07	PP	Acetona		3MM Whatman		1763		2	0	98,583 %	Pass	
				Normal Saline		3MM Whatman		10		757		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-010		05/07/2021 03:31	PP	Acetona		3MM Whatman		854		6	0	99,099 %	Pass	
				Normal Saline		3MM Whatman		3		1474		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-026		05/07/2021 07:12	GF	Acetona		3MM Whatman		628		1	0	99,399 %	Pass	
				Normal Saline		3MM Whatman		4		900		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-029		05/07/2021 07:27	GF	Acetona		3MM Whatman		618		2	0	98,912 %	Pass	
				Normal Saline		3MM Whatman		5		648		pH (Low/Actual/High)	4,00 <= 5,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-030		05/07/2021 07:56	GF	Acetona		3MM Whatman		563		4	0	98,234 %	Pass	
				Normal Saline		3MM Whatman		8		746		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-031		05/07/2021 07:58	GF	Acetona		3MM Whatman		441		2	0	98,80 %	Pass	
				Normal Saline		3MM Whatman		5		663		pH (Low/Actual/High)	4,00 <= 6,00	<= 7,80
												Límpido/Incolor		
MDP-99mTc Lot # K-20210705-039		05/07/2021 10:24	WG	Acetona		3MM Whatman		1021		6	0	96,843 %	Pass	
				Normal Saline		3MM Whatman		22		833		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
MIBI-99mTc Lot # K-20210705-001	05/07/2021	02:02	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1122 13		20 2205	0	pH (Low/Actual/High)	97,663 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-002	05/07/2021	02:03	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			864 80		23 3553	0	pH (Low/Actual/High)	95,205 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-003	05/07/2021	02:57	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1515 73		36 2161	0	pH (Low/Actual/High)	94,411 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-004	05/07/2021	02:58	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1738 30		27 2531	0	pH (Low/Actual/High)	97,299 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-005	05/07/2021	03:02	PP	Normal Saline Metanol	Sílica gel 3MM Whatman			1558 32		52 1795	0	pH (Low/Actual/High)	95,019 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-022	05/07/2021	06:40	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			994 3		28 805	0	pH (Low/Actual/High)	96,889 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-023	05/07/2021	06:41	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			988 35		18 1035	0	pH (Low/Actual/High)	94,94 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-025	05/07/2021	07:10	GF	Normal Saline Metanol	Sílica gel 3MM Whatman			653 5		13 1124	0	pH (Low/Actual/High)	97,605 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20210705-038	05/07/2021	10:20	WG	Normal Saline Metanol	Sílica gel 3MM Whatman			1172 25		23 1562	0	pH (Low/Actual/High)	96,50 %	Pass 5,00 <= 6,00 <= 6,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210705-028	05/07/2021	07:27	GF	Butanona Normal Saline	3MM Whatman 3MM Whatman			215 2		1 239	0	pH (Low/Actual/High)	98,707 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PIRO-99mTc Lot # K-20210705-040	05/07/2021	10:27	WG	Butanona Normal Saline	3MM Whatman 3MM Whatman			406 22		1 494	0	pH (Low/Actual/High)	95,491 %	Pass 5,00 <= 6,00 <= 7,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20210705-024	05/07/2021	06:48	GF	Acetato de amônio	Sílica gel			0,2		34,4	0	pH (Low/Actual/High)	99,422 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20210705-053	05/07/2021	12:45	JS	Acetato de amônio	Sílica gel			0,2		29,3	0	pH (Low/Actual/High)	99,322 %	Pass 4,00 <= 5,00 <= 8,00
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
Tecnício-99m Lot # E-20210705-001	05/07/2021	01:57	PP	Butanona		3MM Whatman		103		5297	0	98,093 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-002	05/07/2021	02:54	PP	Butanona		3MM Whatman		7		888	0	99,218 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-003	05/07/2021	03:01	PP	Butanona		3MM Whatman		4		1081	0	99,631 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-004	05/07/2021	03:28	PP	Butanona		3MM Whatman		44		6821	0	99,359 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-005	05/07/2021	06:28	GF	Butanona		3MM Whatman		2		328	0	99,394 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-007	05/07/2021	07:07	GF	Butanona		3MM Whatman		0		308	0	100,00 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnício-99m Lot # E-20210705-008	05/07/2021	07:25	GF	Butanona		3MM Whatman		1		234	0	99,574 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnício-99m Lot # E-20210705-009	05/07/2021	07:53	GF	Butanona		3MM Whatman		0		227	0	100,00 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-012	05/07/2021	10:16	WG	Butanona		3MM Whatman		13		1119	0	98,852 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnício-99m Lot # E-20210705-013	05/07/2021	10:59	WG	Butanona		3MM Whatman		2		2336	0	99,914 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		