



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 30/12/2021 To 30/12/2021

Product:	Manuf:	Calibration	D/T	QC By	Solution	Media	Origin	Middle	Top	Background	Particle Size/ OK?	% Tag	Pass Fail
DMSA-99mTc Lot # K-20211230-021		30/12/2021	10:03	MB	Butanona Normal Saline	3MM Whatman Sílica gel	115,6 5,6		1,2 116,8	0		94,397 %	Pass
Límpido/Incolor													
DOTATOC-68Ga Lot # K-20211230-011		30/12/2021	06:48	MB	Citrato de Sódio 0,1M	Sílica gel	22,5		0,9	0		96,154 %	Pass
Límpido e Incolor													
DOTATOC-68Ga Lot # K-20211230-024		30/12/2021	12:45	JS	Citrato de Sódio 0,1M	Sílica gel	50,7		0,2	0		99,607 %	Pass
Límpido e Incolor													
DTPA-99mTc Lot # K-20211230-016	RPH	30/12/2021	09:20	PM	Acetona Normal Saline	3MM Whatman 3MM Whatman	477 3		1 454	0		99,134 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211230-001		30/12/2021	02:53	MB	Butanona	3MM Whatman	305		2	0		99,349 %	Pass
Límpido/Incolor													
FITATO-99mTc Lot # K-20211230-012		30/12/2021	07:15	MB	Butanona	3MM Whatman	256		3	0		98,842 %	Pass
Límpido/Incolor													
MAA-99mTc Lot # K-20211230-008		30/12/2021	04:06	MB	Butanona	3MM Whatman	283		3	0		98,951 %	Pass
Turvo/Incolor													
MAA-99mTc Lot # K-20211230-025		30/12/2021	14:04	VS	Butanona	3MM Whatman	594		5	0		99,165 %	Pass
Turvo/Incolor													
MDP-99mTc Lot # K-20211230-004		30/12/2021	03:18	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	804 2		1 795	0		99,625 %	Pass
Límpido/Incolor													
MDP-99mTc Lot # K-20211230-005		30/12/2021	03:22	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	976 11		4 1146	0		98,641 %	Pass
Límpido/Incolor													
MDP-99mTc Lot # K-20211230-006		30/12/2021	03:44	MB	Acetona Normal Saline	3MM Whatman 3MM Whatman	938 45		4 983	0		95,198 %	Pass
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-20211230-009		30/12/2021 06:33	MB	Acetona Normal Saline	3MM	Whatman		145,4 1,6		0,8 111,2	0	pH (Low/Actual/High)	98,034 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211230-013		30/12/2021 07:18	MB	Acetona Normal Saline	3MM	Whatman		227 3		3 230	0	pH (Low/Actual/High)	97,408 %	Pass 4,00 <= 5,00 <= 7,80
Límpido/Incolor														
MDP-99mTc Lot # K-20211230-015		30/12/2021 09:14	PM	Acetona Normal Saline	3MM	Whatman		1170 22		2 1323	0	pH (Low/Actual/High)	98,194 %	Pass 4,00 <= 6,00 <= 7,80
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-002		30/12/2021 02:59	MB	Normal Saline Metanol	Sílica gel 3MM			865 12		16 1172	0	pH (Low/Actual/High)	97,17 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-003		30/12/2021 03:00	MB	Normal Saline Metanol	Sílica gel 3MM			1224 14		17 1476	0	pH (Low/Actual/High)	97,691 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-007		30/12/2021 04:00	MB	Normal Saline Metanol	Sílica gel 3MM			1031 35		14 1733	0	pH (Low/Actual/High)	96,681 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-010		30/12/2021 06:42	MB	Normal Saline Metanol	Sílica gel 3MM			458 10		6 466	0	pH (Low/Actual/High)	96,606 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-014		30/12/2021 08:22	PM	Normal Saline Metanol	Sílica gel 3MM			384 5		8 436	0	pH (Low/Actual/High)	96,825 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-022		30/12/2021 10:02	MB	Normal Saline Metanol	Sílica gel 3MM			587 9		6 569	0	pH (Low/Actual/High)	97,431 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
MIBI-99mTc Lot # K-20211230-023		30/12/2021 11:06	MB	Normal Saline Metanol	Sílica gel 3MM			1163 11		35 1230	0	pH (Low/Actual/High)	96,192 %	Pass 5,00 <= 5,00 <= 6,00
Límpido/Incolor														
PSMA-68Ga Lot # K-20211230-019		30/12/2021 09:50	MB	Acetato de amônio 1M:Metanol	Sílica gel			3		124	0	pH (Low/Actual/High)	97,638 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
PSMA-68Ga Lot # K-20211230-026		30/12/2021 15:38	VS	Acetato de amônio 1M:Metanol	Sílica gel			7		260	0	pH (Low/Actual/High)	97,378 %	Pass 4,00 <= 5,00 <= 8,00
Límpido e Incolor														
Tecnécio-99m Lot # E-20211230-001		30/12/2021 02:51	MB	Butanona	3MM	Whatman		6		849	0	pH (Low/Actual/High)	99,298 %	Pass 5,00 <= 5,00 <= 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-20211230-003		30/12/2021 02:55	MB	Butanona		3MM Whatman		3		559	0	99,466 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-002		30/12/2021 02:55	MB	Butanona		3MM Whatman		4		293	0	98,653 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-004		30/12/2021 03:15	MB	Butanona		3MM Whatman		1		397	0	99,749 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-005		30/12/2021 03:19	MB	Butanona		3MM Whatman		1		206	0	99,517 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-006		30/12/2021 03:40	MB	Butanona		3MM Whatman		8		507	0	98,447 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-007		30/12/2021 03:58	MB	Butanona		3MM Whatman		8		391	0	97,995 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-008		30/12/2021 04:03	MB	Butanona		3MM Whatman		6		597	0	99,005 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-009		30/12/2021 06:19	MB	Butanona		3MM Whatman		4		673	0	99,409 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-010		30/12/2021 06:38	MB	Butanona		3MM Whatman		3		692	0	99,568 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-012		30/12/2021 07:11	MB	Butanona		3MM Whatman		1		93	0	98,936 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-013		30/12/2021 08:13	MB	Butanona		3MM Whatman		5		1352	0	99,632 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 5,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-014		30/12/2021 08:34	JS	Butanona		3MM Whatman		11		975	0	98,884 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 6,00 <= 6,00		
Tecnécio-99m Lot # E-20211230-015		30/12/2021 08:37	JS	Butanona		3MM Whatman		4		1878	0	99,787 %	Pass	
							Límpido e Incolor				pH (Low/Actual/High)	5,00 <= 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
Tecnécio-99m Lot # E-20211230-016		30/12/2021 09:04 PM	Butanona		3MM Whatman			9		731	0	98,784 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211230-017		30/12/2021 09:43 PM	Butanona		3MM Whatman			1		787	0	99,873 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211230-019		30/12/2021 09:56 PM	Butanona		3MM Whatman			6		979	0	99,391 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211230-020		30/12/2021 10:56 MB	Butanona		3MM Whatman			10		514	0	98,092 %	Pass	
											pH (Low/Actual/High)	5,00 <= 5,00	<= 6,00	
														Límpido e Incolor
Tecnécio-99m Lot # E-20211230-022		30/12/2021 13:57 VS	Butanona		3MM Whatman			14		1324	0	98,954 %	Pass	
											pH (Low/Actual/High)	5,00 <= 6,00	<= 6,00	
														Límpido e Incolor
TRODAT-99mTc Lot # K-20211230-017		30/12/2021 09:49 MB	Normal Saline		Sílica gel			108,9		0,3	0	99,397 %	Pass	
			Butanona		3MM Whatman			0,5		151,8	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor
TRODAT-99mTc Lot # K-20211230-018		30/12/2021 09:50 MB	Normal Saline		Sílica gel			97,4		2,2	0	93,605 %	Pass	
			Butanona		3MM Whatman			5,5		125,9	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor
TRODAT-99mTc Lot # K-20211230-020		30/12/2021 09:51 MB	Normal Saline		Sílica gel			89,1		5,1	0	94,086 %	Pass	
			Butanona		3MM Whatman			0,7		139,3	pH (Low/Actual/High)	6,50 <= 7,00	<= 8,50	
														Límpido/Incolor