



Certificate of Analysis

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Date 29/08/2024

Analyzed by: RONIT-N

Approved by: ILANIT-B

Product Name: KCl - Refined Grade USP - Excipient

Catalog No. 0/813/200/653

Batch: 890000915159

Production Date: Aug 12, 2024

Expiry Date: Aug-2027

Version: 0

Test	Method	Specification	Result
Identification			
Identification K	Potassium <191>	Responds to test K+	Pass
Identification Cl ⁻	Chloride <191>	Responds to test Cl-	Pass
Assay "on dry basis"	Monograph	NLT 99.0-100.5%	100.0
Impurities			
Aluminium*	Aluminium <206>	NMT 1.0 mg/kg	
Limit of Sodium	Monograph	No yellow color	Pass
Limit of Iodides	Monograph	NMT 0.005%	Pass
Limit of Bromides	Monograph	NMT 0.1%	Pass
Calcium and Magnesium	Monograph	No turbidity is produced within 5 min	Pass
Elemental Impurities**	<232>, <233>	Pass	Checked periodically
Specific Test			
Alkalinity of Solution	Monograph	No Pink Color	Pass
Acidity of Solution	Monograph	Pink Color	Pass
Loss on Drying	Loss on Drying <731>	NMT 1.0%	0.15

*According to the cUSP customers using product for hemodialysis should test it for aluminum content

** Complies with ICH Q3D Monthly Test, Skip Test – Test Periodically

Signature

29/08/24 ר.ס.3

Signature

29/8/24 אילנית ב

Approval Signature

Print date 29/08/2024

כיל דשנים

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