# PRODUCT SPESIFICATION

## REFINED SALT PHARMA GRADE (PG)

NO.	PARAMETER	UNIT	US. PHARMACEUTICAL								
			SPECIFICATION								
1	Assay **	%	99 - 100,5								
2	Identification Natrium **		Meet requirement								
	Identification Cloride **		Meet requirement								
3	Loss on drying **	%	<u>≤</u> 0,5								
4	lodides **		NIL								
5	Phosphate **	ppm	<u>&lt;</u> 25								
6	Nitrit **		<u>&lt;</u> 0,01								
7	Ca and Mg, as Ca **	ppm	<u>&lt;</u> 100								
8	Acidity 0,01 N/NaOH **	ml	<u>&lt;</u> 0,5								
9	Alkalinity 0,01 N/HCI **	''''	<u>≤</u> 0,5								
10	Ferrocyanides **		Conforms								
	Ba ***		Conforms								
11	As ***		<u>≤</u> 1								
''	Fe ***		<u>≤</u> 2								
	Heavy Metals ***	ppm	≤5								
12	SO <sub>4</sub> ***		<u>≤</u> 200								
13	Appearance of solution **		Colorless & clear								
14	Bacterial endotoxins (pyrogen) ***	EU/g	≤ 5								
15	Total plate count ***		<u>≤</u> 100								
16	Yeasts ***	CFU/gr	<u>&lt;</u> 100								
17	Molds ***		<u>≤</u> 100								
18	Staphylococcus aureus ***	/gr	Negative								
19	Salmonella sp. ***	/10 gr	Negative								
20	Escherichia coli ***		Negative								
21	Pseudomonas aeruginosa ***	/gr	Negative								

<sup>\*\*</sup> Meet requirement U.S Pharmaceutical

## PRODUCT DESCRIPTION:

## **REFINED SALT PHARMA GRADE (PG)**

Refined Salt Pharma Grade is Pharmaceutical Grade Sodium Chloride that produced by PT UNIChemCandi Indonesia since 2019. This product has high purity that produced by refinery technology so this product is suitable for the pharmaceutical industries. Our product was compliance with Pharmacopeia Indonesia and US.Pharmacopeia.

## **COUNTRY OF ORIGIN:**

Made In Indonesia

<sup>\*\*\*</sup> Based on third party laboratory (Sucofindo & Saraswanti Indo Genetech)



#### **SUITABLE USES:**

- Haemodialysis
- Oral Rehydration Salts
- Oral Tablets
- Dietary Formulations
- Infant Formulations

## HIGH QUALITY, HIGH PURITY SODIUM CHLORIDE FEATURES:

- Pyrogen Free
- Oigin Material: Sea Salt
- Low Heavy Metals

## **CERTIFICATION:**

- FSSC 22000
- Halal
- SEDEX

#### **PACKAGING:**

25 Kg Multiwall paper sack with light gauge polyethylene liner Outer: Kraft Paper Material 3 layers (Layer 1: 80 GSM, Layer 2 & 3: 75 GSM) Inner: Polyethylene plastic 100 micron

#### **BATCH MARKS:**

Batch marking on the packaging is in the form SADDMMYY

#### **PALLETS:**

25 Kg packs: Standard pallet configuration is 40 x 25 Kg bags (1 tonnes per pallet)

All Salt is wrapped and strapped on plastic pallets with a paper sheet between the pallet and the salt.

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Authorised by:	Title:	Sign:		M	1	1	\	Date:
Tuluz Widiyanto	Lab & QA Manager		Ħ	1	#	#	MAX	9 November 2021
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