

Minerals play a key role in the human body and in case of their deficiency, the best and fastest way to deliver fluids and medication throughout a patient's body is the intravenous route which enables minerals to be fully absorbed within the body circulation.

**Infusion solutions (IV)** composed from our mineral salts serve as a fast carrier of the most important pure minerals.

Our materials are essential in **dialysis treatment** for patients suffering from kidney failure and are used in hemodialysis (HD) and peritoneal dialysis (PD) and acute care dialysis solutions. Some countries consider HD solution as a medical device whereas it is a drug elsewhere. PD and acute care dialysis solutions are always considered as a drug and therefore all raw materials must be **API**.

Manufacturers of HD, PD, acute care dialysis as well as IV solutions who are searching for **qualified raw material producers** belong to core clients of Macco Organiques.

A dialysis solution has levels of minerals that are similar to their natural concentration in healthy blood. The levels of the components of dialysate are typically prescribed by a nephrologist according to the needs of each individual patient. The typical composition of dialysis solution consists of:

- Calcium Chloride Dihydrate
- Magnesium Chloride Hexahydrate
- Potassium Chloride
- Sodium Chloride

- Sodium Bicarbonate
- Sodium Acetate Trihydrate / Anhydrous or Sodium Diacetate
- Citric Acid / Acetic Acid

The high level of quality is reflected in the certification and registrations awarded to Macco Organiques:

	Chemical production				Product						
	GMP Q7				CEP/CoS	EDFM	US DMF	JDMF	CDMF	KDMF	Taiwan DMF
Туре	Compliance	EU Certificate	US GMP	Jap. Certificate	Certificate	Doc.	Registr.	Registr.	Registr.	Registr.	Registr.
Certification Body	N/A	PIC/S	FDA	Jap. MoH	EDQM	N/A	FDA	Jap. MoH	CDE	Korean MoH	Taiwan MoH
Calcium Chloride 2Hy	✓	✓	1	✓	✓	✓	✓	✓	✓	✓	✓
Magnesium Chloride 6Hy	1	<b>✓</b>	/	<b>✓</b>	1	1	1	1	1	1	1
Potassium Chloride	✓	✓	/	<b>✓</b>	1	1	1	1		1	1
Sodium Glycerophosphate	1	✓	/		in process	1	1				
Sodium Lactate min. 50%	1	✓				/					
Tri-Sodium Citrate Dihydrate	1	<b>✓</b>	/								
Sodium Acetate Anhydrous	✓	Health Canada	1		x	х	✓				
Sodium Acetate Trihydrate	1	Health Canada	/		1	1	1				
Sodium Chloride	1	✓	/		1	1	/				
Sodium Bicarbonate	1	<b>✓</b>	/		1	1	/				

The developing field of **dialysis and infusion solutions** appreciates the flexibility of packaging which Macco Organiques can offer respecting individual needs of each client.

# **Production under**



# **Certification and Registrations:**

GMP Q7, FSSC 22000, ISO 9001, CoS/CEP, DMF, Halal, Kosher, API Facility and DMF registrations at the US FDA

## **Quality Standards:**

EP, BP, USP, JP, FCC, E-numbers, ACS

### Our standard pack sizes:

Low volume sacks and jars (50 g - 5 kg), Bags (10 kg - 25 kg), Carton boxes 25 kg, Plastic drums (12 kg - 250 lb), Fibre drums (25 kg - 250 lb), Big-bags (400 kg - 1 000 kg)

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