Baxter

Bieffe Medital, S.A.
SABIÑÁNIGO (HU) SPAIN
Ctra. de Biescas, s/n 22666 SENEGÜE

Certificate of Analysis

UE1323D-CA Ed.4

Ref. MO1F1US

Code: UE1323D	Batch n°: 24F04E5M	Volume: 500 ml
Check digits: 53	Manufacturing date: 2024-06-04	Expiry date: 2026-05
Product: Sodium Chloride 0.9% w/v	Package type: Plastic bag	Quantity: 17540
Units / carton: 20	Marketing Authorization Number:	Pharmaceutical form: IV
Importing Country: USA	NDC 0338-9543-04	

Comments: n/a

Composition

Ingredient	Quantity	mmol/l	Reference
Sodium Chloride	9.0 g	154.00	EP
Water for Injections to	1000 ml		EP

Analytical Results

Tests	Product Limits	TANK Results 1	TANK Results 2	TANK Results 3	TANK Results 4	References
pH	4.5 - 7.0	5.9	5.9	n/a	n/a	Potentiometric (USP < 791 > / EP 2.2.3)
Sodium id.	Positive	Positive	Positive	n/a	n/a	EP 2.2.22 (Flame Photometry)
Chloride Assay	146.3 - 161.7 mEq/l 8.55 - 9.45 g/l	152.7 mEq/l 8.93 g/l	152.9 mEq/l 8.94 g/l	n/a n/a	n/a n/a	EP 2.2.20 (Automated Potentiometric Titration)
Chloride id.	Positive	Positive	Positive	n/a	n/a	Precioitation + Ammonia Re-dissolution (USP<191>EP 2.3.1)
Extractable Volume	250 mL container = NLT 250 mL 500 mL container = NLT 500 mL 1000 mL container = NLT 1000 mL	540 mL	540 mL	n/a	n/a	Volumetric (USP < 1 > /EP 2.9.17)
Particles	Container 250-500-1000 ml NMT 25 particles/mL ≥ 10 µm NMT 3 particles mL ≥ 25 µm	2 particles/mL ≥ 10 µm 0 particles mL ≥ 25 µm		n/a	n/a	Light Obscuration (Instrumental) (USP <788> / EP 2.9.19)
Sterility*	Sterile	Conforms	Conforms	n/a	n/a	Parametric Release *
Bacterial Endotoxins	≤ 0.25 IU/mL	Conforms	Conforms	n/a	n/a	Kinetic Turbidimetric (USP <85> / EP 2.6.14)

*In lieu of sterility testing, product release is contingent upon meeting process parameters established for the sterilization cycle. The sterility test cannot be used to override a reject decision due to failure to meet a process parameter requirement.

This is to certify that this product (incl API) was manufactured using approved specifications according to current European Union GMP Guidelines and fulfills the requirements of the relevant national marketing authorization. All manufacturing records are controlled and verified meeting GMP practices.

Released by: Qualified Person

Date: 17 Jun. 2024 Signature: T. Abós