

Certificate of Analysis

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T-PAS+ (250ml)

Batch Number 24052016
Manufacture Date 10 Apr 2024
Expiry Date 2026-04-01
Product Number 40853

TEST	SPECIFICATION / LIMITS	RESULT
DESCRIPTION	A nominal volume of 250ml of an aqueous sterile apyrogenic solution is contained in a 350ml non-PVC pack	COMPLIES
APPEARANCE	The solution is clear and colourless. The pack should be transparent in the body and at the ends and ports with no evidence of moisture present. The packs are clearly and correctly labelled for the product contained, with a 24 month expiry date.	COMPLIES
PORTS	The pack has two ports, one has a breakable male luer with a cap and the other has a dock line	COMPLIES
FRANGIBILITY	A sample of 5 packs pass the test and still pass the Resistance To Leakage test	COMPLIES
PARTICULATE CONTAMINATION	A sample of 3 packs when examined do not contain particles of foreign matter that can readily be observed on visual inspection. The mean counts of particles per ml does not exceed $25 \geq 10\mu\text{m}$ and $3 \geq 25\mu\text{m}$.	COMPLIES
ACIDITY	The solution should have a pH of 7.1 to 7.5	7.2
TOTAL SODIUM CONTENT	Lies within the limits of 175 to 192mmol/l Na^+ . This represents 95 to 105% of the theoretical content of 183.8mmol/l Na^+ .	186
POTASSIUM CONTENT	Lies within the limits of 4.75 to 5.25mmol/l K^+ . This represents 95 to 105% of the theoretical content of 5mmol/l K^+ .	5.00
TOTAL CHLORIDE CONTENT	Lies within the limits of 74 to 81mmol/l Cl^- . This represents 95 to 105% of the theoretical content of 77.3mmol/l Cl^- .	77
MAGNESIUM CHLORIDE CONTENT	Lies within the limits of 1.425 to 1.575mmol/l MgCl_2 . This represents 95 to 105% of the theoretical content of 1.50mmol/l MgCl_2 .	1.499
SODIUM ACETATE CONTENT	Lies within the limits of 4.20 to 4.64g/l. This represents 95 to 105% of the theoretical content of 4.42g/l sodium acetate trihydrate.	4.43
SODIUM CITRATE CONTENT	Lies within the limits of 3.02 to 3.33g/l. This represents 95 to 105% of the theoretical content of 3.18g/l sodium citrate dihydrate.	3.19
TOTAL PHOSPHATE	Lies within the limits of 26.6 to 29.4mmol/l. This represents 95 to 105% of the theoretical content of 28mmol/l phosphate.	28.5
ENDOTOXINS	Not more than 5.56 EU/ml	COMPLIES
STERILITY	Complies with the test for sterility	COMPLIES

Approved By



Date



Steven Craythorne, PhD, CChem, MRSC,
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