Baxter Healthcare Corporation

JAYUYA PLANT
PO Box 518
250 Road 144
Jayuya, PR 00664

QPK-80

Certificate of Analysis / Certificate of Compliance

Product: 0.9% Sodium Chloride Inj., USP- 50mL Mini-Bag Viaflex Container

Lot #: P357632
Code: 2B1301
Mixing Spec: 03-15-19-278
Issue Date: 05/16/2008

Quantity Released: 249,504 UNITS
Manufactured Date: 12/08/2016
Released Date: 12/15/2016
Expiry: June 2018

TEST	LIMIT	RESULT
pH at 25 deg. C	4.5 - 7.0	5.6
Sodium Chloride in g/L (M1)	8.55 - 9.45 g/L	8.78 g/L
Sodium ID- Flame	Positive	Positive
Sodium ID- USP	Positive	Positive
Particle Analysis	NMT 120 part / ml $\geq$ 10 µm	0 part /ml $\geq$ 10 µm
Particle Analysis	NMT 12 part / ml $\geq$ 25 µm	0 part /ml $\geq$ 25 µm
Sterility	Pass Parametric Release	PASS
Endotoxin	NMT 0.5 Eu/ml	<0.25 Eu/ml

This certifies that this product was manufactured in compliance with the NDA/ANDAs, cGMP's and company Standard Operations Procedures.

(X) This product meets all products specifications, parametric release requirements and is found acceptable and releasable for distribution in accordance with:

(X) FDA Requirements ( ) Others (specify): _____

12-20-16
Prepared By / Date

12-29-16
Quality Management Approval / Date