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

Certificate of Analysis / Certificate of Compliance

Product: 0.9% Sodium Chloride Inj., USP- 100mL Mini-Bag Viaflex Container

Lot #:	P298000	**Quantity Released:**	166,272 UNITS
Code:	2B1302	**Manufactured Date:**	02/18/2013
Mixing Spec:	03-15-19-278	**Released Date:**	02/22/2013
Issue Date:	05/16/2008	**Expiry:**	August 2014

TEST	LIMIT	RESULT
pH at 25 deg. C	4.5 - 7.0	5.9
Sodium Chloride in g/L (M1)	8.55 - 9.45 g/L	8.79 g/L
Sodium ID- Flame	Positive	Positive
Sodium ID- USP	Positive	Positive
Particle Analysis	NMT60part / ml ≥ 10 µm	0part /ml ≥ 10 µm
Particle Analysis	NMT6part / ml ≥ 25 µm	0part /ml ≥ 25 µm
Sterility	Pass Parametric Release	PASS
Endotoxin	NMT0.5 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): _____ 2/23/13

2/23/13
Prepared By / Date

02/25/2013
Quality Management Approval / Date