Template Provided By:

Cancer Imaging Program

National Cancer Institute

Reagent/Supply Specification Sheet

(Refer to GEN-M001)

Reagent/Supply: **Sodium bicarbonate 4.2% Neutralizing Additive Solution**
Storage Conditions: **Room Temperature**
(if applicable)

Internal Tracking Code: SS-BIC **MSDS On File? Y N N/A**
(circle one)

Suppliers:

Vendor	Address	Telephone Number	MSDS Available	Vendor Designation (If Needed)
American Pharmaceutical Partners, In.	**Schaumburg, IL 60173**	(716) 773-0800	Yes	A

Ordering Information:

Vendor	Product Code	Description	Size/Units	Bulk Quantities	Certificate of Analysis Available
American Pharmaceutical Partners	**2605**	Sodium bicarbonate 4.2% (2.5 mEQ / 5mL), Neutralizing Additive Solution Single Dose Vial, NDC 63323-026-05 2605	5 mL	N/A	Yes

COA Specifications:

Parameter	Test Methodology	Specification	C of A Verification	Comments
Appearance	Visual Inspection	Container is intact Colorless Liquid Passes Test	**Y N N/A**	
Identification	1) Test for Carbonates and bicarbonates 2) Test for Sodium	1) conforms 2) conforms	**Y N N/A**	
Assay	-------	95.5% to 105% of label claim	**Y N N/A**	
Sterility	------	0.0005% (maximum) or 5 ppm	**Y N N/A**	
Particulate Matter	------	Does not exceed 1) 6,000 particles ≥ 10 microns per container 2) 600 particles ≥ 25 microns per container	**Y N N/A**	
Bacterial Endotoxins	------	MNT 5.0 EU/mEq	**Y N N/A**	

Internal Specifications: For all non-USP reagents, the certificate of analysis will be compared with the listed internal specifications to ensure that the manufacturers are still testing the product consistently and utilizing the same standards to determine quality, purity, and identity of the reagents.

Regulatory Affairs Approval: _____ **Date:** _____
Signature

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