GenA-L **Master Compounding Record for Production of Gentisic Acid (0.25g/100ml saline)**

Preparation of Gentisic Acid (0.25g/100mL saline) -_____

Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume		Calculated Amount
Gentisic Acid	**SS-GentA-_____**	**0.25g/100mL**	**x**	**100 mL**	**=**	**0.25g**
0.9% Sodium Chloride (USP)	**SS-NSI-_____**		**x**		**=**	**100mL**
2.0M Sodium Carbonate	**NaCO-L-2.0M-_____**					**1.0 mL**

Applicable Operating Procedures and References:

1. **MPR-[^{89}Zr]Protein**, "Master Production Record for Synthesis of [^{89}Zr]Protein Injection"

Materials and Equipment:

1. Analytical Balance
2. Graduated cylinder, 200 mL (to deliver)
3. 0.9% Sodium Chloride
4. Labels
5. Pyrogen free 50ml graduated tube
6. pH 5.0-10.0 strip

Guidelines:

- Use clean dry graduated cylinders.

STEPS
1. Weigh 0.125g of Gentisic Acid to a Pyrogen free 50ml graduated tube. Add 30ml of 0.9% Sodium Chloride to the tube.
2. Add 0.2ml Na2CO3 to the tube and homogenize until no more CO2 is formed (release pressure in tube). Check pH and acceptance pH range: 4.9-5.3.

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3. Fill the tube with 0.9% NaCl till the marked line.
4. Cap the flask and mix the contents thoroughly. Label the container with the contents, date made and the initials of the person who made the solution. Label with an expiration of 1 day.

Performed By/Date: _____ Checked By/Date: _____

QA Review: _____ Date: _____

PSOP: GenA-L Master Compounding Record for Preparation of Gentisic Acid Solution	Supersedes**: None**
Effective Date**:**	Version**: V1**

Printed Name	Signature	Date
Author:		
Regulatory Approval:		

Procedure becomes effective on latest date of the two approval signatures above.
Procedure applies to all IND drugs.

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