Template

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Not Responsible for Investigator's Use

CITRICA-L Master Compounding Record for Preparation of TLC Mobile Phase for QC

Preparation of TLC Mobile Phase for QC -_____

Raw Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume		Calculated Amount
Citric Acid	**SS-CitricA-_____**	**20mM**	**x**	**100ml**	**=**	**0.42g**
Water (CHELEX)	**CHELEX-L-_____**		**x**		**=**	**100ml**
2.0 M Sodium Carbonate	**NaCO-L-2.0M-_____**					**0.98ml**

Applicable Operating Procedures and References:

1. **Form-Q311**, "Standard Operating Procedure Radio -Thin Layer Chromatography Analysis"

Materials and Equipment:

1. Analytical Balance
2. Graduated cylinder, 100 mL (to deliver)
3. Water, HPLC graded
4. Labels
5. Pyrogen free 100ml bottle
6. pH 2.0-9.0 strip

Guidelines:

- Use clean dry graduated cylinders.

STEPS
1. Weigh 0.42g of Citric Acid to a Pyrogen free 100ml bottle. Add 50ml of HPLC graded water to the bottle.
2. Add 0.98 ml of 2.0 M Na2CO3 to the bottle and homogenize until no more CO2 is formed (release pressure in bottle). Check pH and acceptance range: 4.8-5.0.
3. Fill the bottle with HPLC graded water to 100ml.
4. Cap the flask and mix the contents thoroughly. Label the container with the contents, date made and the

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initials of the person who made the solution. Label with an expiration of 6 months.

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

QA Review: _____ Date: _____

SOP**: Citric-L Master Compounding Record for Preparation of TLC Mobile Phase for QC**	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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