Template Provided By:

Cancer Imaging Program

National Cancer Institute

Master Compounding Record

Preparation of 0.5 M HCL

Raw Material Bill of Materials, sterile supplies and Calculations Record (only applicable if using conc. HCl)

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume (mL)		Calculated Amount (mL)
Hydrochoric Acid, 36.5-38.0%, NF	SS-HCL-_____	0.5 M = 0.5 N	x	1000	=	42
Sterile Water for Injection	SS-WFI-_____	balance	x		=	~958

Raw Material Bill of Materials, sterile supplies and Calculations Record (only applicable if using 1.0 M HCl solution)

Component Name	Internal Tracking Number (ITN)	Desired Concentration	x	Target Volume (mL)		Calculated Amount (mL)
Hydrochoric Acid, 1 M standard solution Eu Ph	SS-HCS-_____	0.5 M = 0.5 N	x	500	=	250 mL
Sterile Water for Injection	SS-WFI- _____	balance	x		=	250 mL

Raw Material Bill of Materials, only applicable if using 0.5 M HCl solution

Component Name	Internal Tracking Number (ITN)	Desired Concentration
Hydrochloric Acid, 0.5 M standard solution Eu Ph	SS-HCS-_____	0.5 N

Materials and Equipment:

1. Laminar Flow Hood ISO Class 5, clean
2. Disposable Sterile, Pyrogen-free Syringes with Needles
3. Glass or Polypropylene Containers for Final HCl solutions, pyrogen-free and dry with caps lined with Teflon®, polyethylene or polypropylene
4. Glass Volumetric Flask or Graduated Cylinders, depyrogenated
5. Plastic or glass beaker, depyrogenated and dry for solution transfer.
6. HCL (**SS-HCL**), concentrated or 1 N solution EuPh or 0.5 N solution EuPh. (**SS-HCS**)
7. Sterile Water for Injection, USP, (**SS-WFI**)
8. Labels

Guidelines:

- Dilute the HCl within a laminar flow hood using aseptic technique.
- For HCl, 0.5 N = 0.5 M
- Wear appropriate safety gear, including safety glasses and gloves

GEN-Compounding Record HCL-L Version: **V0**

Author:_____**Date:**_____ .

Regulatory Approval:_____**Date:** _____.

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STEPS
1a. **<u>If using concentrated HCl</u>:** Rinse a 1 L volumetric flask with water for injection and discard the water. Fill the volumetric flask ~ half full with water for injection. Rinse a graduated cylinder (TD) with HCL and discard the acid. Add 42 mL of concentrated HCl to the graduated cylinder and then pour into the volumetric flask. Add water for injection to the full mark of the volumetric flask. Cap and mix the contents thoroughly. **Volume of HCl added to the graduated cylinder: _____ mL** *Note: volumes can be scaled for other size volumetric flasks.* **Size of flask used: _____ mL** **Total final acid solution concentration (M) = _____M** Proceed to step 2.
1b. **<u>If using 1.0 M HCl</u>**: Rinse a 500 mL depyrogenated graduated cylinder (TC) with a small amount of water for injection, discard the water. Add 250 mL of water for injection to the graduated cylinder. A: **Volume of water added to the graduated cylinder: _____ mL** Then add 250 mL of 1.0 M HCl to the graduated cylinder. B: **Volume of water + acid added to the graduated cylinder: _____ mL** C: **Volume of acid added to the graduated cylinder: _____ mL (**= *B minus A***)** Total final acid solution concentration (M) = _____ M (= *C/B)* Proceed to step 2.
1c. **<u>If using 0.5 M HCl</u>**: No dilution is necessary. Proceed to step 2.
2. Add the acid solution to the beaker / container for transfer. Swirl the beaker to mix the acid solution in the container. Draw up the 0.5 M HCl solution with a large syringe and needle and aliquot 2.5 to 3 mL each into pyrogen-free glass or plastic vials. Cap the vials.
3. Label the vials as follows: **HCL-_ -_____** **0.5 M HCl _____ Prepared By: _____** **Date:_____Expires: _____** **<u>NOTE</u>**: The HCL solution expires 6 months after preparation when stored sealed at room temperature.

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

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