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Master Compounding Record

HES-L-_____

Compounding Record for the HPLC Aquasil Column Mobile Phase

Approval Signatures:

Printed Name	Date	Signature	Date
Author:			
Supervisor:			
Regulatory Affairs/QA:			

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Compounding Record for the HPLC Aquasil Column Mobile Phase

Raw Material Bill of Materials and Calculations Record

Component Name	Internal Tracking Number (ITN)	Desired Concentration (% = v/v)	x	Target Volume (mL)		Calculated Amount (mL)
Methanol (HPLC grade)	**SS-MTH-L_____**	**14 %**	**x**	**500**	**=**	**70**
Water (HPLC grade)	**SS-HGW-L_____**	**86%**	**x**		**=**	**430**

Applicable Operating Procedures and References:

1. **GEN-Q119**, "Chemical and Radiochemical Purity by HPLC"
2. Kateman G., Buydens L. Quality Control in Analytical Chemistry, second ed. John Wiley & Sons, Inc. New York. 1993. 317 p.

Materials and Equipment:

1. Graduated cylinders, 100 mL and 500 mL (to deliver)
2. Methanol, (SS-MTH)
3. HPLC grade water, (SS-HGW)
4. Labels
5. Final Container(s) for Storage with appropriate Lid

Guidelines:

- Use clean dry graduated cylinders.
- If the HPLC pump system has the ability to input both the methanol and water separately into the pump system prior to mixing them, then add the water and methanol into the pump input lines separately. Program the pump to make the eluent 86% water: 14% methanol (v:v) mobile phase within the pump.

STEPS
1. Add 430 mL of HPLC grade water in the 500 mL graduated cylinder, after rinsing the cylinder with the HPLC grade water.
2. Add 70 mL of HPLC grade methanol in the 100 mL graduated cylinder, after rinsing the cylinder with the HPLC grade methanol. Add the methanol to the water in step 1.
3. Pour the mobile phase into the final storage container, cap the container, and mix the contents thoroughly. Label the container with the compounding number, contents, date made, and the initials of the person who made the solution.

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

QA Review: _____ **Date:** _____

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REVISION HISTORY

Version Number	Description	Reason for Revision	Date	Author
V0	Original Record	Original Record	March 1, 2005	Teresa R. Zuber

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