# PBS-HPLC-L Master Compounding Record for Preparation of Analytical HPLC Mobile Phase

***Preparation of Analytical HPLC Mobile Phase -_____***

**Raw Material Bill of Materials and Calculations Record**

| Component Name | Internal Tracking Number (ITN) | Desired Concentration | x | Target Volume | | Calculated Amount |
|---|---|---|---|---|---|---|
| **Sodium Azide** | **SS-NaN3-_____** | **0.65g/L** | **x** | **1L** | **=** | **0.65g** |
| **Water (HPLC)** | **SS-HGW-_____** | | **x** | | **=** | **1L** |
| **PBS 10M** | **SS-PBS10M_____** | **0.05M** | | | | **5ml** |
| **Sodium Chloride 5M** | **SS-NaC5M_____** | **0.15M** | | | | **30ml** |

**Applicable Operating Procedures and References:**

1. **&Žd**Ŵ **-Q118**, "Standard Operating Procedure for Determination of Concentration of DFO-Pan by HPLC"
2. **&Žd**Ŵ**-Q319**, "Standard Operating Procedure of HPLC for 89Zr-Protein"
3. **&Žd**Ŵ**-Q320**, "Standard Operating Procedure of Analytical HPLC for DFO-Protein"

**Materials and Equipment:**

1. Analytical Balance
2. Graduated cylinder, 50ml, 1L (to deliver)
3. Water, HPLC graded
4. Labels
5. Pyrogen free 1L bottle

**Guidelines:**

- Use clean dry graduated cylinders.

| STEPS |
|---|
| 1. Weigh 0.65g of Sodium Azide to a Pyrogen free 1L bottle. Add 500ml of HPLC graded water to the bottle |

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| and dissolve the Sodium Azide. |
| 2. Transfer 5ml of 10M PBS and 30ml 5M Sodium Chloride to the 1L bottle. |
| 3. Fill the bottle with HPLC graded water to 1000ml. Check pH with pH paper. Acceptance range: pH 6.2-7.0. |
| 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 6 months. |

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

**QA Review: _____ Date: _____**

SOP**: PBS-HPLC-L Master Compounding Record for Preparation of Analytical HPLC Mobile Phase** 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.*

DRAFT