**Tutorial on IPT Station**

As an IPT technician, it requires you to perform a total of 9 tests.

1. Moisture Content
2. Scorched Particle analysis
3. Bulk Density
4. pH reading
5. Grain analysis
6. Floater & Sinker analysis
7. Phase separation analysis.
8. Sediment Analysis
9. Extraneous Matter Analysis

|  |
| --- |
| **When conducting analysis** |
| 1. Ensure PPE is worn - sanitized gloves, goggles and mask. 2. Be very patient to get precise results. 3. Get a piece of paper to write down the results. 4. Keep the sink dry when handling liquid components/mixtures. 5. Label the correct samples. 6. Use the correct equipment with the correct label and place the correct sample in the correct equipment. Everything by the book with labels. 7. If KimTech Glass Wipes have runned out, collect another box from the A Lab. (Analytical lab) 8. Refill purified bottles with purified water from the homogenizer or A lab. |

|  |  |
| --- | --- |
| **Explanation of roles** | |
| **Technician** | **Front Line Leader** |
| Perform required in process sampling and analysis with appropriate aseptic technique. Comply with cGMP & EHS requirements. Labeling samples for microbiology laboratory with relevant information. | Review papers and electronic documentation made by technicians and take corrective action if necessary. Ensure compliance to cGMP & EHS. Technicians are proficient in use of in process sampling and analysis equipment |

**Table of Contents**

**Chapter 1**

1.1 pH Standardization Test 3

1.2 Standard Operating Procedure on pH Standardization 3

1.3 Day of use pH standardization sheet 4

**Chapter 2**

2.1 Moisture Content 5

2.2 Scorched Particles Analysis 5

2.3 Bulk Density 6

2.4 pH Reading Analysis 6

2.5 Grain Analysis 7

2.6 Floater & Sinker Analysis 7

2.7 Phase Layer Separation Analysis 8

2.8 Sediment Analysis 8

2.9 Extraneous Matter Analysis 9

**Chapter 1**

**1.1 pH Standardization Test**

|  |  |  |
| --- | --- | --- |
| **When** | **Solutions used** | **Materials needed** |
| To be performed at the start of each shift, i.e 0800 or 2000, simply say every 12 hours | 1. pH 7 buffer solution - 19H074103 2. pH 4 buffer solution - 20B184130 | pH standardization sheet - to be recorded down by performer and verified by any dryer technician |

* 1. **Standard Operating Procedure on pH Standardization**

1. Ensure buffer solution (pH 4) to be changed every 4 days.

1. Throw away and replace the previous shift with a new pH buffer solution for both 7.00 and 4.00 solutions before performing standardization. Ensure the beaker is for the correct solution as it has already been clearly labelled.
2. Once replacement is done, place pH buffer solution 7.00 onto the magnetic stirrer, rotating at speed 2, and place the pH probe with it being cleaned with purified water and wiped dry with KimTech Glass Wipes.
3. Wait for 5 mins then press ‘Enter’ then ‘Std’ on the pH meter then wait for another 3 mins. After 3 mins, press ‘Std’ again. Read the pH level and write down on the pH standardization sheet.
4. Remove the pH probe and repeat step 4 but with pH buffer solution 4.00. Also write down the slope value on the pH standardization sheet.
5. Once done performing standardization, clean the pH probe with purified water and wiped dry with KimTech Glass Wipes.
6. Place the pH rod into the buffer solution.
7. Ensure the pH standardization sheet has been verified by any dryer technician upon completion of standardization.

**Chapter 1**

**1.3 Day of use pH standardization sheet**

|  |  |
| --- | --- |
| **Title** | **What to write** |
| Equipment Owner | Under ‘Others’ - Write MFG |
| Model of pH meter | Tick ‘Accumet pH Meter’ |
| Equipment ID | Write ‘SN06MET0036 |
| Date & time performed | Write current date, time and performers signature being tested |
| Lot no. for buffer 1 | Current code used for pH 7 |
| Lot no. for buffer 2 | Current code used for pH 4 |
| Lot no. for buffer 3 | Write ‘NA’ |
| Expiry date for buffer 1 | Current date used for pH 7 |
| Expiry date for buffer 2 | Current date used for pH 4 |
| Expiry date for buffer 3 | Write ‘NA’ |
| pH value on label | 7.00 for buffer 1 |
| 4.00 for buffer 2 |
| Write ‘NA’ for buffer 3 |
| Slope value | Slope value of pH 4 (buffer 2) after standardizing |
| Offset value | Write ‘NA’ |
| Meet acceptable criteria | Tick ‘Yes’ if slope value is =<92% - =>102%, if no, perform standardization again. |
| Reviewed by | To be reviewed, signed and dated by any dryer technician. |

**Chapter 2**

**2.1 Moisture Content**

|  |  |
| --- | --- |
| Description of analysis | Performed to read the total amount of moisture present in the spray dry powder. |
| When to perform? | Every 2 hours.  After startup.  Heightened sampling. (if order is given) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | Depending on the product, if above or below the acceptable range, escalate. |
| What happens if there is a problem? | Product will not be dried enough thus causing lifespan of a product to deteriorate and be shortened. |
| Reaction plan | Adjust following parameters, mainly from the vibrofluidizer area. |
| Cause of moisture being off-specification | Fluctuation of total dissolved solids in the vibro fluidizer. |

**2.2 Scorched Particles Analysis**

|  |  |
| --- | --- |
| Description of analysis | Performed to detect any burnt particles. |
| When to perform? | Every 2 hours.  Heightened sampling. (if order is given) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | If it is under category C or/and D. |
| What happens if there is a problem? | Consumers will taste a burnt taste in the product and feel like eating sand and hurts the throat especially to infants. Quality of product will be affected. |
| Reaction plan | Adjust the parameters, mainly the temperature controller from the UHT. (Ultra Heating Treatment) |
| Cause of being off-specification | Excessive exposure to high temperature during drying which may result in scorching discolouration insolubility. |

**Chapter 2**

**2.3 Bulk Density**

|  |  |
| --- | --- |
| Description of analysis | Performed to calculate the bulk density of a product. |
| When to perform? | Beginning Of Batch. (BOB)  After startup. |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | Depending on the product, if above or below the acceptable range, escalate. |
| What happens if there is a problem? | Bad image and reputation towards the company as they might feel that we are cheating their money. |
| Reaction plan | Divert to rework. |
| Cause of being off-specification | Unstable production/drying of the total solids in the dryer. |

**2.4 pH Reading Analysis**

|  |  |
| --- | --- |
| Description of analysis | Performed to detect any hi or low pH. |
| When to perform? | Beginning Of Batch. (BOB)  Middle Of Batch. (MOB)  End Of Batch. (EOB) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | Depending on the product, if above or below the acceptable range, escalate. Mostly below 6.70 |
| What happens if there is a problem? | Infants/babies' bodies could be harmed due to the low pH and will be bad for consumption towards them. It can also cause degradation to the product and may affect other processes and equipment. |
| Reaction plan | Continue production. (if above 6. 67)  Divert to silo to go for unplanned CIP. (if below 6.65)  Divert to rework. (if below 6.55) |
| Cause of being off-specification | Fouling which produces acid in the evaporator. |

**Chapter 2**

**2.5 Grain Analysis**

|  |  |
| --- | --- |
| Description of analysis | Performed to detect any protein denaturation in a product. |
| When to perform? | Beginning Of Batch. (BOB)  Middle Of Batch. (MOB)  End Of Batch. (EOB) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | If it is under category grain 4 - 6. |
| What happens if there is a problem? | Presence of cations may result in side reactions with protein storage conditions unfavorable to protein stability. Feels like eating sand towards infants. |
| Reaction plan | Adjust the parameters, reduce the temperature in the UHT (Ultra Heating Treatment) treatment. |
| Cause of being off-specification | High process temperatures in particular, occurring UHT treatment. |

**2.6 Floater & Sinker Analysis**

|  |  |
| --- | --- |
| Description of analysis | Perform to Identify undissolved particles which either settle to the bottom of the mixed powder or float to the top of the mixture. |
| When to perform? | Every 2 hours.  Heightened sampling. (if order is given) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | Depending on the product, if above the acceptable number of floaters or sinkers, escalate. |
| What happens if there is a problem? | Bad reputation for the company as mothers will not like to see, especially floaters which can have a bad image. |
| Reaction plan | Stop production and divert to rework. Perform investigations after bag off and during reproduction of rework powder. |
| Cause of being off-specification | Foreign objects/materials. |

**Chapter 2**

**2.7 Phase Layer Separation Analysis**

|  |  |
| --- | --- |
| Description of analysis | Performed to detect if there are any loss of uniformity in the product |
| When to perform? | Beginning Of Batch. (BOB)  Middle Of Batch. (MOB)  End Of Batch. (EOB) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | If there is more than 1 layer. |
| What happens if there is a problem? | Consumption and taste may vary. |
| Reaction plan | According to A lab instructions. |
| Cause of being off-specification | Caused by fat separation of product destabilization resulting in formation of unusual obstruction at top and bottom phases. Homogenisation did not homogenise well. |

**2.8 Sediment Analysis**

|  |  |
| --- | --- |
| Description of analysis | Performed to detect any scorched particles that are caught on to the filter. |
| When to perform? | Every 2 hours.  After startup.  Heightened sampling. (if order is given) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | If the filter disc is not clean and clear of small burnt particles. |
| What happens if there is a problem? | Quality problem. |
| Reaction plan | Reduce parameters from the UHT areas. |
| Cause of being off-specification | Excessive exposure to high temperature during drying may result in scorching discolouration insolubility |

**Chapter 2**

**2.9 Extraneous Matter Analysis**

|  |  |
| --- | --- |
| Description of analysis | Performed to detect any black particle event occurring during production. |
| When to perform? | Every 2 hours.  After startup.  Heightened sampling. (if order is given) |
| When to escalate to FLL (Front Line Leader) and/or dryer technician | Black particle event occurs. |
| What happens if there is a problem? | EM occurrence may potentially affect product safety. |
| Reaction plan | Perform investigations by placing filter socks at these 5 areas.   1. After the vibro fluidizer 2. Before the high-pressure pump in the evaporator room 3. Before the UHT feedline 4. After The UHT feedline 5. From the FPT   After investigation, divert to rework. |
| Cause of being off-specification | Foreign materials, objects and metals may enter in any open manway, holes or gaps. |

Done by: Shahrul Aswad (Intern)