1. DESCRIPTION OF DEVIATION:

To meet the customer requirement for sevelamer carbonate material LOD specification, atmospheric drying was performed in FBD. Change control has been initiated.TC: No: CUD/RCI-2021-247. As proposed 25.0 kg (from Drum no: 03) Sevelamer carbonate batch. No: CSCF210229 material was taken for humidification trial by using FBD at ambient temperature then sample will be submitted for LOD by HMA analysis.

Trial-I:

FBD Drying samples (For information) were submitted from parent batch No :CSCF210229 at 2nd and 3rd hr. interval for LOD by HMA analysis. During each sampling 2 kg of material was collected and stored. Analytical details as tabulated below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Input batch. No | Input qty | Drying time | LOD by HMA | Material taken | Remarks | Available remaining qty |
| 03/11/2021 | Trial-I CSCF210229 | 25.0 kg | 120 mts | 15.229 | 2.0 kg | Drying performed Apprx-85%RH) | 21.00 kg |
| 180 mts | 22.074 | 2.0 kg |

Trial-II

Due to higher range of LOD result further trial was planned with 10.0 kg of same batch material. Trial-II details are as tabulated below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date | Input | Input qty | Drying time | LOD by HMA | Material taken | Remarks |
| 05/11/2021 | Trial-II batch. No CSCF210229 | 10.0 kg | 10 mts | 5.257 | 1.0 kg | Drying performed Apprx-65%RH |
| 20 mts | 5.826 | 1.0 Kg |
| 30 mts | 6.328 | 1.0 kg |
| 60 mts | 9.665 | 0.5 kg |
| 90 mts | 14.756 | 0.5 kg |
| 120 mts | 17.43 | 0.25 kg |

Based on CFT discussion the following four samples has been selected and labelled as below batch numbers & sampling done by QC (Packing seal not provided) and sent to RAD for LOD by TGA analysis. Details are as below. All below mentioned materials are available except **SCF21229T-C**

|  |  |  |  |
| --- | --- | --- | --- |
| Batch. No | Sample description | IPQC result-% LOD by HMA | RAD result- %LOD by TGA |
| CSCF21229T-A | 60 mts | 9.665 | 10.88 |
| CSCF21229T-B | 90mts | 14.756 | 15.85 |
| **CSCF21229T-C** | **120 mts (Drying performed Apprx-85%RH)** | **15.299** | **14.8** |
| CSCF21229T-D | 120 mts (Drying performed Apprx-65%RH) | 17.439 | 18.90 |

● Outcome of RAD result, LOD result of 15.229% material (Labelled as CSCF21229T-C ) was considered and same material was labeled as CSCF21229T.PAR qty-1.80 kg and manual PAR given on 10th Nov.

● On date 12/11/2021 sampling performed by QC

●On date12 /11/2021 l15.0 kg of material was taken and kept separately in PS-IX. Since LOD by TGA results are in border hence additional planned by CFT.

●CSCF210229-Out put qty- 222.25 kg. 25+10 kg material taken and trial has performed.15.0 kg material kept separately for trial. Remaining material 172.00kg PAR-Qty given . Sampling done by QC for complete analysis on.

●All trial performed in FBD#9 hence materials are kept at 1st floor FBD#9 processing area. However, CSCF210229 materials are stored at PS-1X-Ground floor accordingly additional qty 15.0 kg material kept in same PS-IX.All material are deducted in SAP.

● On date it was observed that 15.0kg material from Batch. No: CSCF210229 storge container QC sampling label as well as packing seal observed. Subjected container weight cross verified and 250 gm weight found less, which proven sampling performed from this container.

●No seal and QC sampling label was observed in batch no CSCF21229Tand weight of container was cross verified and found same.

Conclusion:

Based on investigation it was concluded that sampling performed in CSCF210229 (15.0KG) container instead of CSCF21229T (1.80 kg) container.