

Evaluation non conformity

Used abbreviations:

AT tests : Audit Test
 HA : Hygienic aspects
 IQC : Internal Quality Control
 BRT : Batch Release Test
 PVT : Process Verification Test
 CoA : Certificate of Analyse

Table 1. Product related 3)

| Non-essential requirements 1) | Non Critical | Critical |
|-------------------------------|--------------|----------|
| Incidental | X | |
| Structural | X | |
| Essential requirements 2) | | |
| Incidental | X | |
| Structural | | X |

- 1) Test matrix with exception of AT tests
 2) AT Tests (conform Test matrix)
 3) For HA related non conformities, see table 3

Table 2. IQC related 3)

| Indirect related to product quality 4) | Non Critical | Critical |
|--|--------------|----------|
| Incidental | X | |
| Structural | X | |
| Direct gerelateerd aan productkwaliteit 5) | | |
| Incidental | X | |
| Structural | | X |

- 4) Calibration, Control on incoming goods, Storage and Transport, Complaints
 5) BRT and PVT tests, Treatment of products with deviations

Table 3. Hygienic Aspects related

| Non-essential requirements 6) | Non Critical | Critical |
|-------------------------------|--------------|----------|
| Incidental | X | |
| Structural | X | |
| Essential-requirements 7) | | |
| Incidental | | X |
| Structural | | X |

- 6) No (correct) HA-appendix at the factory, Marking, same ingredient from other supplier, CoA out of specification, no valid EMG report available, contamination potential not ok
 7) Use of not evaluated ingredients or components. Construction of the product/ composition is not according to the HA-appendix (same ingredient from other supplier), contamination is present. At doubt, contact the certification engineer.