PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

# PSM案例学习：
## 从一起物料的自燃事件看变更管理的重要性
## PSM Case Study: MOC's role in a smoldering incident

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事件分析 Cause Analysis

经验学习 Lessons Learnt

# 嘉宾介绍 Speaker Bio

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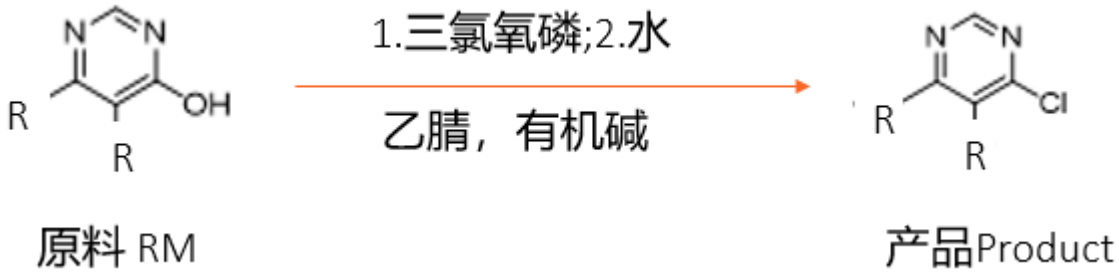
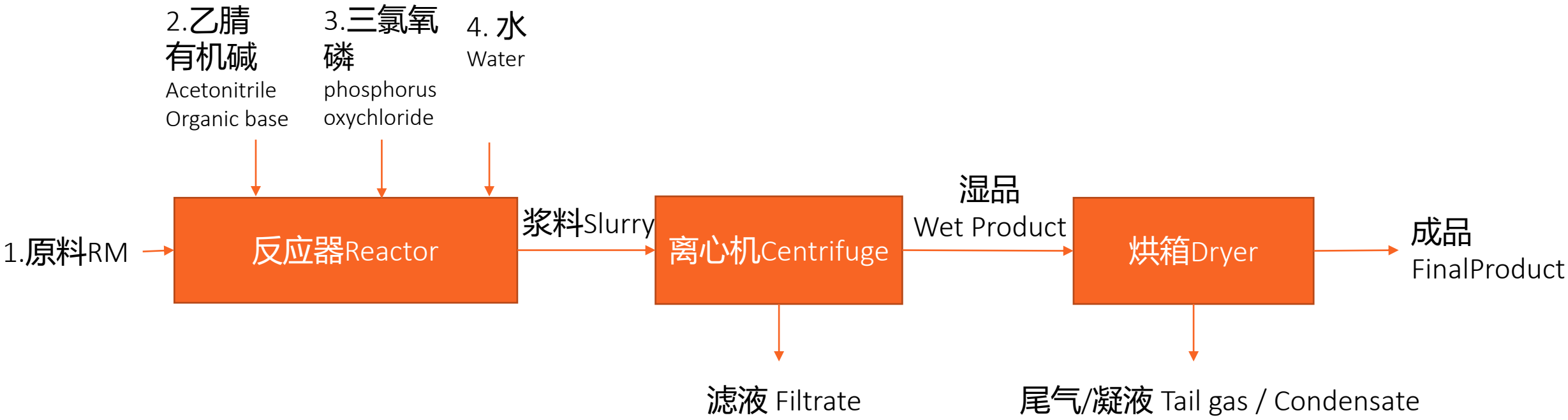
# 1. 事件简介 Incident Introduction

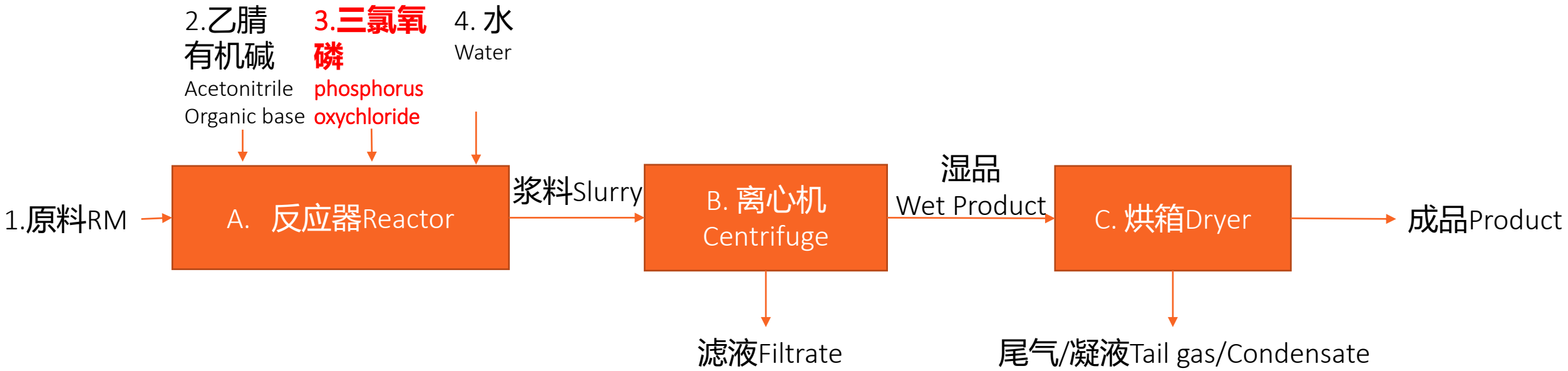
- 当日凌晨02:30分，操作人员将离心出来的3袋共80kg返工湿品物料存放于储存间；
- At 2:30, one operator stored 3 bags (80kg) of centrifugal reworked wet product into storage room,.
- 06:00许，车间湿品物料发生冒烟并起火。火情被周边巡检人员及时发现，并被及时消灭。
- At 6:00, smoke and fire appeared from the wet product, which was found by an operator who was in patrol nearby and extinguished it out immediately.

# 2. 工艺简介 Process Introduction



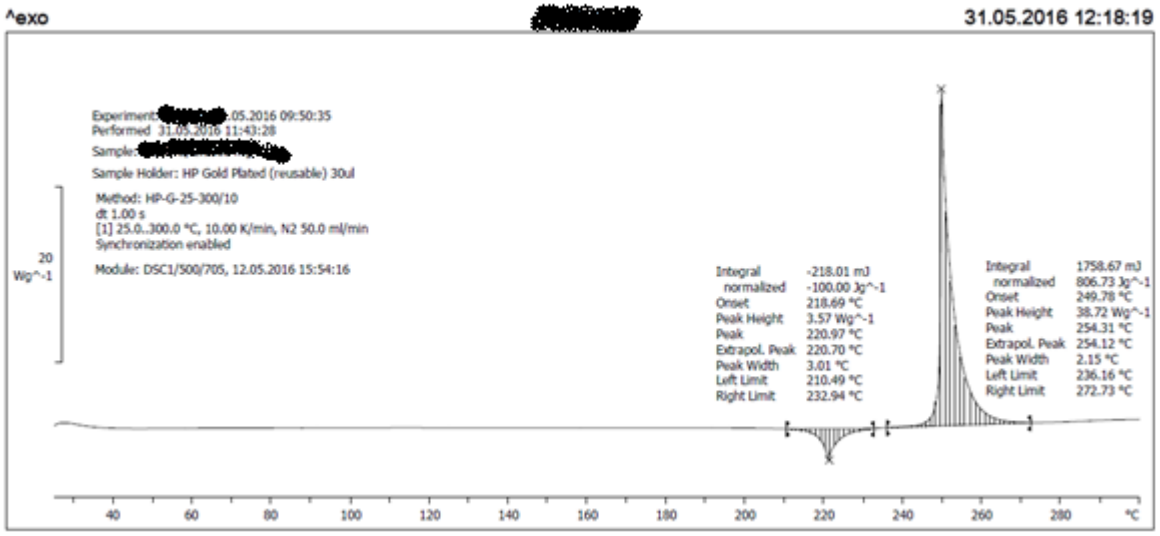
# 3. 事件经过 Incident Details



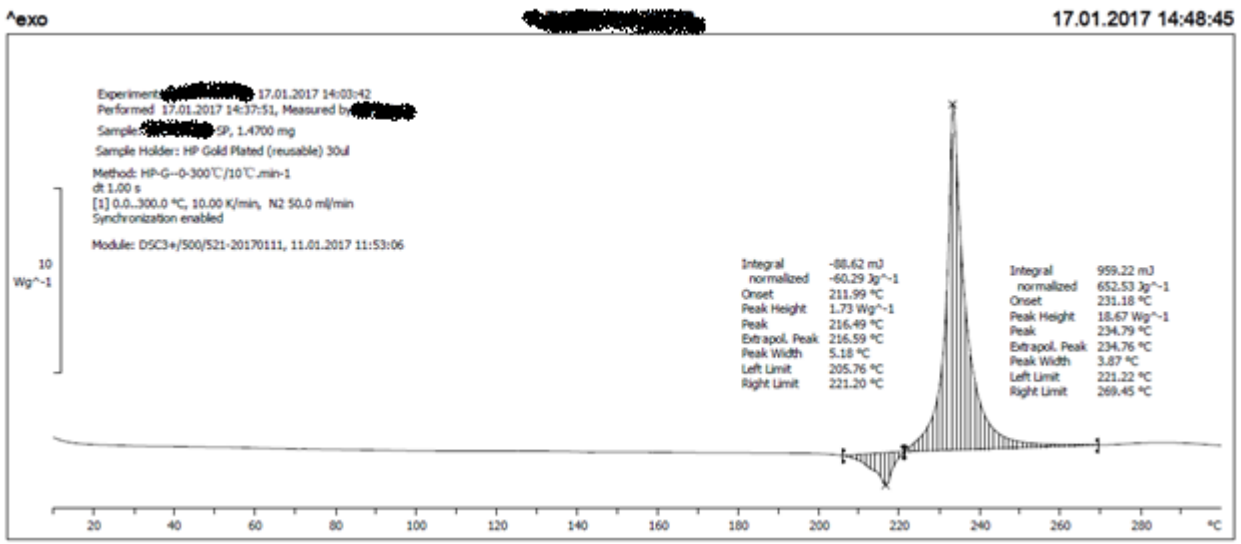

- 事发前批次反应，在加完三氯氧磷后（A.3），由于工艺原因，大量原料RM未完成反应。
- In the last batch before the incident, because of the process, after feeding phosphorus oxychloride (A.3), loads of RM didn't react completely.
- 当晚经与技术人员讨论后，决定直接往后面做至离心（B），回收原料RM。
- After discussion with technician, they decided to do until centrifuge step (B), and recycled the RM.
- 次日凌晨2时，离心得到回收的原料RM湿品，并存放于暂存间。
- 2:00am the next day, they got the recycled wet RM, and put into the storage room.
- 次日凌晨6时，操作人员巡检时发现暂存间冒烟。
- 6:00am, the operator found smoke came out from storage room in patrol.

# 4. 事件分析 Incident Analysis

事故前物料测试数据 Material test data before the incident：




原料RM干品
Dry RM

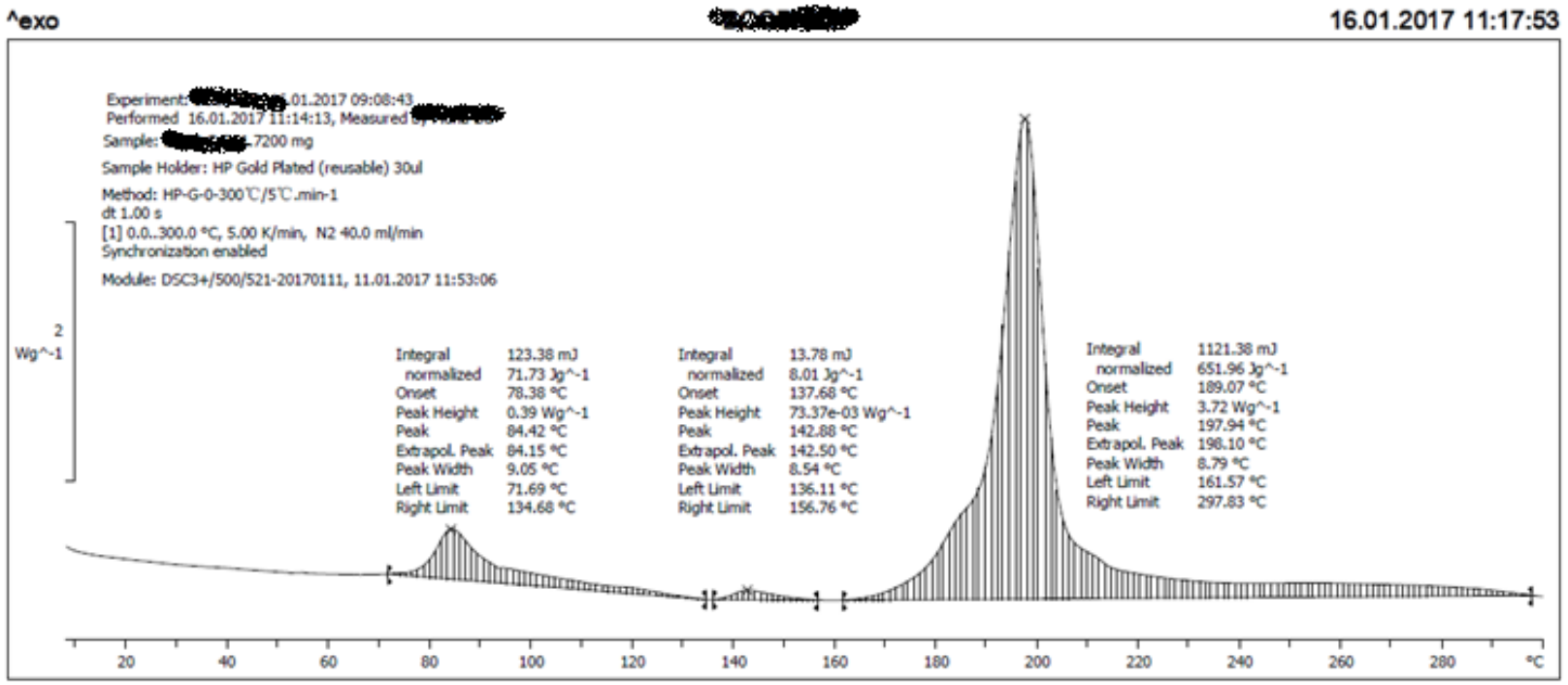



原料RM湿品
Wet RM

# 4. 事件分析 Incident Analysis

事故后补充测试 Supplemented test data after the incident：

回收原料 Recycled material




回收原料RM的DSC

DCS of reworked RM

初始放热Initial heat release 1：

T0=71℃，Q’=71.7J/g；

初始放热Initial heat release 2：

T0=136℃，Q’=8J/g；

初始放热Initial heat release 3：

**T0=161℃，Q’=651J/g；**

# 4. 事件分析 Incident Analysis

事故后补充测试 Supplemental test data after the incident：

回收原料 Recycled material

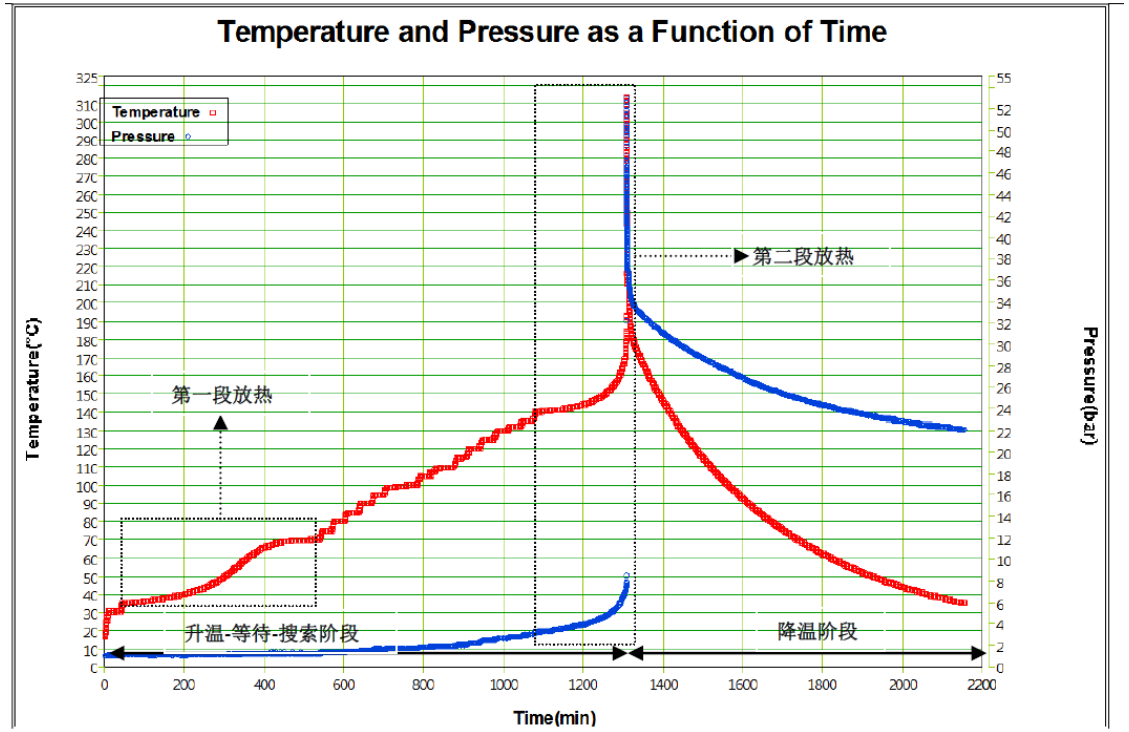



图 1. 整个测试过程样品温度（红色）&样品压力（蓝色）随时间变化曲线

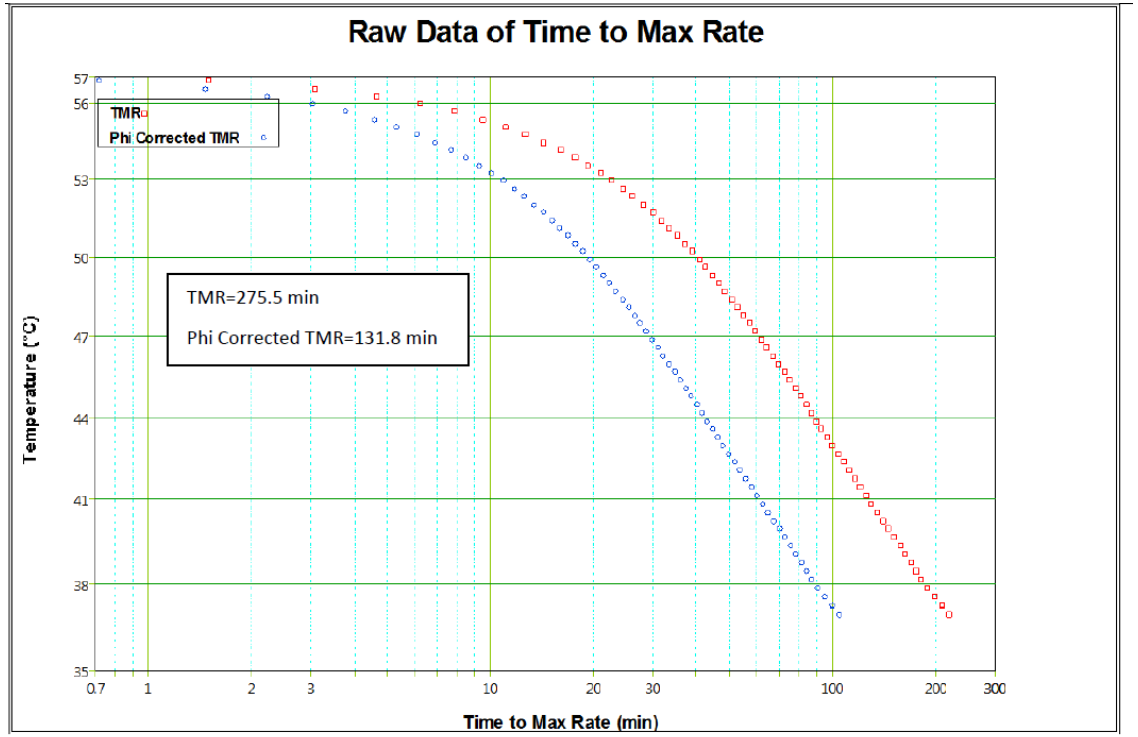



图 5. 第一段放热过程中Φ值校准过的 TMR 曲线（蓝色）与原始 TMR 曲线（红色）

起始放热Initial heat release 1：T0=35.4℃，绝热温升ΔTad：71.5℃；
起始放热Initial heat release 2：T0=140℃，绝热温升ΔTad：362℃，

TMR=131.8min=2.2h

# 4. 事件分析 Incident Analysis

- 湿品杂质分析 Impurity analysis of wet product

| | 磷 P<br>ppm | 氯 Cl<br>ppm | pH |
|---|---|---|---|
| 正常批次Normal Batch | 102 | 647 | 6-7 |
| 回收（事故）批次<br>Recycled (Incident) Batch | 19800 | 200 | 1-2 |

# 5. 经验学习 Lessons Learnt

- 工艺的任何变化，特别是对于含有高能或高活性化学品的工艺，必须及时对安全数据重新进行评估。

In any process change, especially including high-energy or highly reactive chemicals, safety data should be assessed properly in time.

- 对于高能化学品，特别警惕杂质对其稳定性的影响，常见的杂质有：

For high-energy chemicals, more caution should be paid to its stability impact caused by impurities, classical impurities includes:

- 铁锈 Iron rust
- 酸碱度 pH
- 水份 water
- 工艺杂质 Process impurity

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About the Secretariat
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