LABTEC
Scientific & Technical Services

Laboratory Notes

APRIL 2012

SERVICES TO AGCHEM

- New Product Development
- Trial Batch Manufacture
- Stability Studies to APVMA & ACVM criteria
- Analytical Method Development and Validation
- CIPAC test-methods
- Routine Quality Control Testing and Shelf-life Extension testing

Seven Sins of Product Stability Data

So, you have this fantastic new addition to your agricultural chemical product range and are rearing to get it to market. Waiting for the regulatory process to run its course can be frustrating enough but when you get data rejected this can result in even longer delays and missed sales opportunities. Many of these delays are avoidable and often stem from poorly conducted stability trials or overseas suppliers not being familiar with the Australian and New Zealand data requirements.

Waiting for new product approvals to be granted can be a frustrating time

Listed below are seven common pitfalls and ways to avoid them:

1.The formulation tested isn't the one to be commercialized.

It seems obvious but the supplied data should relate to the declared formula to be registered. State it as a fact and cross reference any formulation batch codes where available.

2. The trial batch size was too small.

The lab batch size should be large enough to be representative of commercial production processes. The APVMA require that this should be at least 5 litres (or kilograms).

3. The trial was not conducted in commercial packaging.

If the product is to be sold in 25L HDPE jerricans then demonstrating that it is stable in a 20ml glass vial is not particularly helpful. Ideally, the smallest commercial pack should be used for stability trials but a scaled down pack size, constructed of the same polymer, is also acceptable.

4. The trial was conducted at an inappropriate temperature or duration.

If the product failed after 14 days at 54°C then other conditions are also admissible. The next appropriate equivalent is 8 weeks at 40°C. Demonstrated stability at either of these conditions would normally support a 2 year ambient shelf-life. Other equivalent conditions must be technically justified.

5. The analytical methods used for the active were inappropriate.

To effectively monitor any degradation of the active, the test method should be capable of separating out any breakdown products. The techniques of HPLC and GC are particularly useful for this. Other methods, commonly used for routine product QC testing, may not indicate stability (e.g. UV/Vis).

6. The analytical test methods used for the active were not validated correctly.

The data assessor wants to have confidence that the stability data you have supplied can be trusted. The APVMA publish an excellent guideline covering the criteria to be used to verify whether the analytical method is capable of giving accurate and precise results. The requirements are quite prescriptive and the method validation report should be clear and uncluttered so the assessor can tick all those boxes!

7. The product stability report is too brief, or, too long.

Assessors have a pile of work to get through so make it easy for them. Supply exactly what's required, no more and no less.

If you make it too hard then you're likely to end up at the bottom of that pile!

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