DSS050: Dust Explosion Hazards in Pharmaceutical Industries with Dr. Ashok Dastidar
dustsafetyscience.com

In this episode of the DustSafetyScience Podcast, we interview Dr. Ashok Dastidar about dust explosion hazards in pharmaceutical industries.

Ashok, who appeared on Episode #7, is the Vice-President of Dust and Flammability Testing and Consulting Services at Fauske & Associates and a fellow engineer at Westinghouse Electric Company. He is also a member of several NFPA technical committees and the chair of a ASTME 27 committee on the hazardous potential of chemicals.

This topic resulted from a listener-submitted question. They wanted to know how to evaluate dust issues in the pharmaceutical industry. There are diverse product lines, some of them proprietary and with insufficient test data. What should be done with regard to combustible dust hazards?

When discussing solutions, Ashok also answers questions like the following:

- What does a typical processing line in a pharmaceutical plant look like?
- Where are the most hazardous areas?
- How can a safety envelope help make pharmaceutical processes safer?
- What are the general guidelines for dust testing volume?
- What is the standard amount of dust needed for Pmax and KST testing?
- What are common testing challenges?
- What are the recommended ways of doing a DHA in an engineering review of the testing process?

What Does A Typical Processing Line In A Pharmaceutical Plant Look Like?

Generally speaking, the processing line in a pharmaceutical plant is similar to any other chemical line or process system. The industry is

batch-reactor driven as opposed to CSTR or plug flow. Raw ingredients are introduced, usually in a wet state after the addition of water or a chemical solvent. After the reaction is complete, the reactive material is dried out, typically using an autoclave or a centrifugal process. It is then collected using a cyclonic action, with fines going to some type of dust collector.

Where Are The Most Hazardous Areas?

There are hazards present at different stages of the processing line.

At the beginning, there may be the possibility of a static discharge because dry powder is being introduced into a tank. That hazard is further compounded if that medium in the bottom of the tank is not water, but is a flammable solvent. Later on in the process, once the material is wet, it's not so much of a hazard from a dust explosion point of view, but you might have a flash fire or solvent vapor deflagration.

After the solvent is removed and the material has been dried out, suspended dust becomes a potential hazard. This is also a risk when several dry ingredients are being mixed together. This material is then dumped into a process line for shipping to another location, where there may be combustible dust hazards at transfer points. If there are any cyclones, bag houses or cartridge filter areas to collect fugitive materials or even collect the final product for bagging, additional hazards exist. At any stage involving dry material, there will be dust issues due to the fine particles.

Ashok noted that there is not a single formulation from beginning to end. There is a chain of operations that create a drug. For example, there could be 300 possible reagents used that would, in turn, create a huge number of different intermediates that might generate another 100 different possible products that I might be generating.

“How do I then design for all the possible permutations?” Ashok asked. “Unlike dealing with vapors and gases, which are a molecule of fuel reacting with a molecule of oxygen to create a deflagration event, here we have a solid particle with no single particle size distribution or particle morphology. Your solvent content will also vary. So will the explosibility parameters. So by and large, a recommended way to tackle this is to create a safety envelope.

The Safety Envelope Explained

Ashok explained the safety envelope as follows:

“Of the 300 powders and distributions that I’m dealing with, maybe I have 50 of them tested and break those 50 up into different families of chemicals or molecules. I have them tested. I find that for a given family of materials, the Pmax doesn’t exceed a eight bar. The KST never exceeds the 70 or 75 bar-m/s. The MIE never goes below 30 millijoules and the MEC never goes above 100 grams per cubic meter.

You then use these values to design your mitigation and prevention strategy for this process. Then, as new molecules are being generated and new ingredients are being substituted, you’d have them tested to see if they compromise the envelope that you had created or not. And if they do compromise it, then it might be a situation where alternative approaches or materials have to be looked at.

He pointed out that some plants handle over 1,000 chemicals, making it cost prohibitive to test everything. If the materials can be broken down into particle size distributions to create a test matrix, you can create a bell curve to ensure that this family of materials never exceeds a certain explosion severity or ignition sensitivity level.

Dr. Dastidar mentioned that he advises companies who handle chemicals to get explosibility information about the material from their supplier, who can roll the cost into the sale price.

“If, for example, the data shows that none of the KSTs or Pmax values for a molecule exceed 300 bar meters per second and it never exceeds nine-bar over pressure, I will use that information to devise a methodology for sourcing kilogram scale lab equipment.

“So if I’m only looking at a smaller dust collector, maybe I’ll design it to handle 300 bar meter per second. Maybe at that level I’ll use more of the suppression system as opposed to a venting system where I use a combined venting and suppression system so I can properly tackle it. Or maybe I won’t do any of that at all, but use a total inerting system and run everything under nitrogen because the volumes are still small enough that I can effectively inert. I don’t have to go to deflagration protection through suppression or venting.

“So those kinds of strategies really need to be looked at. You can change various materials as you need to and still realize that a better return on your equipment investment. When you use a safety envelope approach, your return on investment doesn’t have a smaller return window. It has it has a much larger return window because you can have a piece of equipment that has a longer life.

What Are The General Guidelines For Dust Testing Volume?

When asked about general guidelines for dust testing volume, Ashok said that he typically asks for somewhere between 75 and 100 grams of material for the go/no go test, so he can get enough repeats. He also recommended packaging it into 10-gram lots, to avoid waste.

“If we end up proving that it explodes using only 20 or 30 grams of material, the other 70 grams can be used for other research avenues that you’re trying to pursue with that molecule. That way, you were not contaminating a whole sample by opening up and exposing the whole 100 grams.”

Ashok said that nitrogen inerting might be more appropriate for lower quantities. That way, you don't have to go up to a 500 gram quantity or more for KST determination. 100 grams could be used for MIE or MEC determination and 100 to 200 grams for LOC determination.

"MIE determination might be more important for you when you're at that bench top scale or KG scale where you can use nitrogen inerting," he said. "Then you can wait to do the KST and the MEC testing when you get to larger scale unit operations where you'll have enough material present. In that case, you know you're going to go to a one ton production environment, in which case you do several small batches at the KG scale so that you do have enough material to then source the larger type of product."

What Is The Standard Amount For Pmax And KST Testing?

For most chemicals, 500 grams is sufficient for Pmax and KST because they usually peak at around 250 to 500 grams per cubic meter. You need a lab to process it to sub 75 microns and sub 5% moisture. However, if your material peaks at 1250 grams per cubic meter or 1500 grams for cubic meter, you might need to have that 1000 grams sample set. Doing additional MIE and MEC testing will not add a lot of mass because small amounts are being tested.

What Are Common Testing Challenges?

When asked about common testing challenges, Ashok identified the following issues.

Unique Products

Unique products can be an issue, as they can limit the amount of material available for testing.

“(For some clients), one gram is worth $1,000,” he explained. “That’s how precious the material is. Maybe you don’t necessarily do the whole host of testing: you just need to know whether you’re compromising that explosion envelope that you want. So instead of doing the three full series in the 20-liter chamber, you do one series. Because you’re not doing as many repeat tests, you reduce the material requirements that are necessary to obtain data, and the data is not as concrete as it would be. The margin of safety you need to add might be slightly higher. But there is that tradeoff.”

Lack of Dialogue

Another challenge he identified was that people send samples to Fauske for testing and don’t want to have a dialogue afterwards. “That’s unfortunate because we could be more effective if we can sit down and discuss what you hope to gain out of the testing and why you want to do the test the way you want to do it.”

Materials Toxicity

Some materials being tested can be hazardous for the personnel working with them. The pharmaceuticals might be life-saving drugs at the milligram level, but when they’re being handled at the 10 to 30-gram level, they can be toxic.

“That’s where communication comes in. When you’re sending in a sample for testing, you really need to be totally upfront with the lab in terms of what kind of molecule they are dealing with. What kind of combustion products could be generated from this from this pharmaceutical ingredient? If an uncontrolled deflagration were to occur at your facility, what kind of toxic products could your fellow workers be exposed to in an accident scenario?”

Problems With Hybrid Mixtures

Ashok said that he sees a higher percentage of hybrid mixture problems when solvents are being used. Certain solvent wet materials can be an issue and if they are not completely dried off afterward, the powder could have some light volatile materials associated with it.

“The other thing is this: exactly how much solvent is there if you just do a moisture analysis?” he said. Some of that could be moisture, some of that could be solvent. How much of it is truly solvent? That’s a hard thing to determine. So, yeah. And that’s probably one of the impediments that we see a lot of versus other industries that involve solvent wet material.”

When testing those hybrid mixtures, Ashok said that during the reactor stage, he tries to simulate the level of solvent vapor that could be present during the actual upset scenario. Then he tries to replicate that solvent concentration within the test vessel at the time of testing.

“If that solvent concentration is high enough to be combustible, the flame dynamics of the solvent is what’s going to govern the combustion hazard assessment, not necessarily the powder itself. So but we need to have that consideration in there.”

What Are The Recommended Ways Of Doing A DHA In An Engineering Review Of The Testing Process?

Ashok said that when you do a DHA in an engineering review of your process, you could end up with a degree of safety if you only partially inert, because when you go down to lower levels of oxygen, the initiating energy level goes up higher.

“So in other words, let’s say if I have my MIE at 21%, oxygen might be 30 millijoules.” he said. “But if my oxygen level were to drop down at

14%, my MIE now be over a thousand millijoules, whereas the LOC of the material might be 8% oxygen. What that goes to tell us is that if (for example) I'm in a spray drying operation and the only thing I'm worried about is electrostatic hazards, perhaps my reaching the LOC level of 8% is not required. I do have a margin of safety with 14% oxygen because now all credible ignition sources are eliminated. MIEs are now greater than 1000 millijoules and my spray drying operation really won't generate static discharges greater than 300 millijoules."

DHAs need to be performed as per NFPA, but a DHA may highlight other solutions. The hazard analysis can provide those different performance-based options that might not be immediately apparent from the outside looking in.

Conclusion

The pharmaceutical industry has several explosive risks during all stages of the development, scaling, and manufacturing processes. Understanding these risks via intensive testing and controlling them can improve safety when handling and processing explosive pharmaceutical substances.

If you would like to discuss further, leave your thoughts in the comments section below.

You can also reach Ashok Dastidar directly:
Email: dust@fauske.com or dha@fauske.com
LinkedIn: https://www.linkedin.com/in/ashok-dastidar-26aa1514/

If you have questions about the contents of this or any other podcast episode, you can go to our 'Questions from the Community' page and submit a text message or video recording. We will then bring someone on to answer these questions in a future episode.

Resources Mentioned

DustSafetyScience:

Combustible Dust Incident Database

DustSafetyScience Podcast

Questions from the Community

Companies:

Fauske & Associates

Organizations:

NFPA

Standards:

ASTM E27

Reports:

Seven Basics of Combustible Dust Sampling and Testing

KST and Pmax Testing for Combustible Dust: Who or What Are They?

How to Collect and Ship Combustible Dust Samples for Testing

Incidents:

West Pharmaceutical Dust Explosion

Previous Podcasts:

DSS007: Dust Hazard Analysis and Explosion Prevention with Dr. Ashok Dastidar