Transcript for “Streamline the tableting process with a co-processed excipient”

Nigel Langley: Hi everyone. My name is Nigel Langley and it gives me great pleasure to host a podcast series. And today with our latest edition of the podcast is one concerning co-processed excipients. And before we get into the detail of what co-processed excipients are all about, I have two special guests today that I'd like them to introduce themselves to you. And that's Ashish and João. So, Ashish, would you mind introducing yourself, and some background?

Ashish Joshi: Thank you, Nigel. It's great being here and, João, it's great to see you too as well. My name is Ashish Joshi and I am the, Technical Manager in Pharma at BASF. I focus on, our excipients that are used in many different dosage forms, and specifically oral dosage forms. As part of my job, I deal with a lot of different excipients including quite a few co-processed excipients that have been successfully used in oral dosage forms.

Before BASF, I have a lot of extensive experience in other excipient industries. Also, focusing on quite a few other co-processed excipients and their use in oral dosage forms. So, I will be happy to share whatever knowledge I have about co-processed excipients. And let’s hope it will be a great discussion with, the three of us.

João Assis: Thanks, Ashish and thanks Nigel. My thanks, Nigel, especially for the invitation here. It is a pleasure to be here with you today. So, I'm João Assis. I'm the Global Technical Marketing Manager, responsible for the Orals Platform here at BASF. And my role at BASF is work and develop case studies using our materials to share with our teams here and share this information with our customers.

Nigel Langley: That's great. Thanks Ashish and João. That's, obviously you're both experts in this area and that's fantastic for our listeners as well, of course. And, Ashish, maybe you could, let's start with you, and I have a sort of general question Before we get involved again with the co-processed excipients, maybe you can describe for the benefit of our listeners who are not familiar with this area, what an excipient is. What, basically, a brief description of what an excipient is and what does it do?

Ashish Joshi: Yeah. So, very, simply if I have to explain an excipient, let’s consider you, take a tablet or a capsule that you normally, take for, say, pain relief or, headache or, allergy or whatever it is. The active part of the tablet is really, small. The active ingredient, as we call it, the API or the active pharmaceutical ingredient, is in a very small amount.

But, to deliver that to the right place in the right manner, in the right form, you need a, bunch of other ingredients, which are called inactive ingredients. So, they themselves do not really help in the healing of the problem, but they help to deliver the drug to the right place in the right form. And all these inactive ingredients are, collectively known as excipients.

Nigel Langley: So thanks, Ashish, for that. That's a great definition. That's very helpful, the definition of excipient. So João, it would be also good if you could just define, very briefly for the audience, what a co-processed excipient is and what, some of the benefits are for co-processed excipients.

João Assis: Sure, Nigel. So, co-processed excipients are the combination of two or more excipients that do not chemically interact with each other. The coprocessing covers improved physical properties and performance characteristics that cannot be achieved by simple physical mixing. The main objective when we develop a co-processed material is to enhance the material properties required to produce drugs, especially through direct compression, optimizing product performance and overcoming blend and processing challenges of drugs.

Nigel Langley: That sounds fantastic. It's exciting then, what co-processed excipients can provide to the pharmaceutical formulator and, Ashish, can you expand a little bit on that? how they're received and what formulators do with co-processed excipients, and, also for the manufacturing potential for these?

Ashish Joshi: Traditionally, pharmaceutical products, especially solid dosage forms, have been manufactured using a very elaborate process of some sort of a granulation, either wet granulation or dry granulation, or multiple blending steps followed by compression. And the entire process is long. It's tedious. There are areas where things could go wrong because there're just way too many processes that are happening, one after the other.

So, the advantage with using a co-processed excipient is, as João mentioned, you are essentially combining the functionality and the benefits of three or four or five different excipients into one. It reduces the number of materials that you use by that much. It reduces the amount of processing that you do by that much. Essentially, you are simplifying the process. You are using less materials. And, you are eliminating, a lot of different, chances of variation in the process. Essentially when, all these co-processed excipients are used, it simplifies the process, makes it faster, and makes it a lot more, reproducible with less chances of things going wrong.

On another interesting aspect of co-processed excipients is~~,~~ as I mentioned before, you have this long granulation process that used to be used before. And now, you can convert that into a very simple, straight forward, direct

compression process which will allow any pharmaceutical company to, have a faster development cycle for their new products, and they can also launch their new products much faster by doing so. And at the same time, can also save a lot on costs and time and labor cost.

Nigel Langley: So, João, maybe you can add to that if you have something to add on, you know, from the formulator benefit. There's obviously more utility, with these co-processed excipients, as Ashish described. And there also seems to be a manufacturing angle here as well, so is that something you can sort of elaborate a little bit on, the manufacturing part?

João Assis: Yes, it seems like not only the manufacturing but also from the development point of view, when you are developing new drugs, new materials, new medicines, we need to work on design of experiments. The way, so we can simplify the way. You can reduce the complexity of, checking different materials because working with a co-processed material can, optimize your performance. And so, avoiding, the selection of one, two, three or four.

Also, Ashish had mentioned this, and the idea as to, okay, let's evaluate, the drug, characteristics. For example, a micronized drug that is more cohesive require different, special excipients. Normally, when you are just working with a simple blend of mixing of excipients you cannot achieve, for example, a direct compression. So, in the manufacturing point of view, we can work with co-processed excipients to overcome these challenges, and just avoiding using a wet granulation. Also, Ashish mentioned that. So, we can go directly to a direct compression, a much straighter forward process. So, reducing costs and time and expedite time to market.

Nigel Langley: That's fascinating and, you know, also can you comment a [00:09:00] little bit for the listeners on... I guess there's quite a few co-processed excipients that have been developed over the years and introduced into the industry. And, would you see this area increasing in its understanding and acceptance? And, do you still see a lot of innovation potential here to generate and develop even more co-processed excipients in the future? if you do, what's the driver behind that?

João Assis: Yes and companies are looking for a more, streamlined process. So, it’s possible using special excipients like co-processed materials. Companies, like BASF or others are developing new materials specially to overcome these challenges. And if industries are more willing to test because they see the benefit of using this material for direct compression. So, we want to reduce the manufacturing cost. We want to expedite the drug development. So, companies are developing more excipients like this, like co-processed, just to better support, formulators when they are developing drugs.

Nigel Langley: Really good. And Ashish, do you have any sort of, area to contribute here? Do you have, anything that we, like to add to?

Ashish Joshi: Yeah. In a short sentence, what I could say is, the drugs of tomorrow cannot be formulated by using the old, traditional, excipients that were developed, probably, three, four, five decades ago. That's a fact. And the new drugs are very complicated. They have issues with solubility, flowability and compressibility. You absolutely need to have, excipients that can stand up to these new drugs of today and be able to formulate them.

Having said that, most of the co-processed excipient focus on solid dosage forms has been on, let's say, improving the compressibility, improving the flow, improving the tablet lubrication effect, improving the mouth feel of a dosage form. Perhaps another area that, eventually I'm sure a lot of excipient manufacturers will be going into is, possibly adding some sort of an excipient, into this co-processed mix which will allow, to enhance the solubility of these active ingredients.

Because, as we know, most of the newer chemical entities that are used as active ingredients, have very poor solubility. And if they have poor solubility, that means they are not going to have good bioavailability and not going to have good effectiveness when administered in a human body. So, adding this solubilizer into this mix of co-processed excipient could be a future area, where companies could think about working on and developing something in, that area.

João Assis: And it's interesting, Ashish, and I want just to mention about, new drugs that are being developed. Normally as you mentioned, it has a low solubility, and we need to normally micronize these drugs. And so, for... For example, for a class two, class four, that has a low solubility.

And it's quite challenging to work with these kinds of drugs by direct compression because of the particle size distribution of these drugs' impact, especially on the flowability and compressibility. So, it's hard to make only a blend of excipients to overcome this, to get in a direct compression process. Co-processed material can help us on that. Providing good flowability, provide great compressibility, and if you are working in an immediate release tablet, also we need to focus on, fast disintegration, to not impact on the solution and the bioavailability.

So, co-processed can give us this, with their, superior properties, can overcome all these challenges.

Nigel Langley: So, in summary, I guess we can say that co-processed excipients have utility in the innovative space, for innovation companies. But also, equally important, I would say probably in the generic industry. Would you concur with that?

João Assis: Yes. And in generic, we need to especially time is, important and we need to work in, very fast developing, product, with a high quality. So, work with a material, like co-processed excipients. So, we can expedite time to market, and providing a very high quality. Co-processed can provide fast development, in a high-quality way.

Nigel Langley: And Ashish, I think you had a comment as, also to, to add.

Ashish Joshi: One of the most common areas where generic industry, uses co-processed excipients is to, let's say they want to make a generic version of an existing, branded product that is going off patent. More likely than not the branded product was manufactured, many years ago, most likely by using a complicated wet granulation process.

Now the generic industry, thanks to co-processed excipients, can make a similar formulation with similar effectiveness with almost similar excipients. And, instead of going the lengthy pathway of doing a wet granulation, and a lot of different complicated processing, now they can just use a multifunctional, co-processed excipient, mix it with the active pharmaceutical ingredient and just do a direct compression.

And that's going to allow them to make the formulation faster. And the formulation is going to be as effective as the branded product. And it will allow the generic industry to have a lot of cost savings by doing so, which is, which is very important for generic industry. And finally, they will be able to launch the product also quite fast, and that is also a big requirement for the generic industry, is to be able to launch products really fast on the market so that they can get the benefit of being the first to file, and so on, so forth.

Nigel Langley: So, there's a lot packed into that, isn't there, for co-processed excipients. And, what I'd like to do now I think, this is actually concludes our discussion today. I'd like to thank both of you for your expertise and your very valuable input. I think, hopefully the listener now understands a lot more about co-processed excipients than they did coming into the podcast. And with that, I'd like to thank everybody for your time and your interest. Thank you.

Ashish Joshi: Thank you.

João Assis: Thank you.