BERLIN PACKAGING HEALTHCARE

FROM ACTIVE INGREDIENT TO PACKAGING – UNDERSTANDING WHAT YOUR HEALTHCARE PRODUCT NEEDS

How Ingredient Sensitivity Can Guide Formulation, Dosage Form and Packaging Decisions

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FOREWORD – THE NEXT STEP IN OUR HEALTHCARE PACKAGING SERIES

In the first article in this series, **"Choosing the Right Packaging for Your Healthcare Product,"** we looked at packaging selection from the perspective of the finished product.

The starting point was simple: before choosing a packaging material, we need to understand what the product needs protection from. Is it sensitive to **moisture, oxygen or light?** From there, we considered how dosage form, barrier requirements and active packaging technologies influence packaging selection.

The key message was that **successful packaging selection begins with understanding the product, not the package.**

In this second article, we take that principle one step further – by moving one step backwards in the product development process.

Before asking whether a finished tablet, capsule, powder or softgel is sensitive to moisture, oxygen or light, we should understand **why it may be sensitive in the first place.**

Often, the answer can be found in the active ingredients.

Vitamins, minerals, botanical extracts, probiotics, oils and other healthcare ingredients have very different sensitivities. Understanding these early can help guide formulation and dosage-form decisions – and eventually the packaging system.

The process therefore becomes:

Active ingredient → ingredient sensitivity → formulation and dosage form → product testing → required barrier → packaging system

This does not mean that a particular ingredient automatically requires a particular packaging material. The final decision must be based on the complete formulation, intended shelf life and appropriate stability testing.

At Berlin Packaging, we believe healthcare packaging should start with what is inside the package, understand what it needs, and work from there towards the right packaging system.

START WITH THE ACTIVE INGREDIENT

A finished tablet or capsule may look extremely stable. The active ingredient inside it may not be.

Formulation, concentration, excipients, coating and manufacturing process can all influence finished-product stability. Nevertheless, the inherent sensitivity of an active ingredient provides an important early warning.

If an ingredient is oxidation-sensitive, oxygen should be part of the development discussion. If it is hygroscopic, moisture protection matters. If it is photosensitive, transparent packaging deserves careful evaluation.

The active ingredient therefore becomes the first step in the decision tree.

VITAMINS – SMALL INGREDIENTS WITH VERY DIFFERENT REQUIREMENTS

Vitamins illustrate why apparently similar healthcare products can require very different protection.

Vitamin A is sensitive to oxidation and light. **Vitamin C** is well known for oxidation sensitivity and can also be affected by moisture. Among the **B vitamins**, riboflavin (B2) is particularly light-sensitive. **Vitamin D** can be affected by oxidation and light, while **vitamin E**, although itself an antioxidant, can also degrade through oxidation.

The term *vitamin product* therefore tells us very little about the packaging requirement.

We need to know which vitamin, in which formulation and in which dosage form.

MINERALS – OFTEN STABLE, BUT NOT ALWAYS SIMPLE

Minerals are generally more chemically stable than many vitamins, but certain mineral salts can be hygroscopic.

Moisture uptake may affect powder flow, tablet hardness, disintegration and physical appearance. Iron can additionally promote oxidation reactions involving other formulation components.

This is particularly relevant for multivitamin and multimineral products, where interactions between ingredients can change the stability profile.

Packaging decisions should therefore be based on the **complete formulation**, not simply individual ingredients.

OILS AND FATTY ACIDS – OXYGEN BECOMES CRITICAL

Unsaturated oils and fatty acids can be particularly susceptible to oxidation.

Omega-3 fatty acids, including EPA and DHA, are important examples. Oxidation can affect potency as well as taste and odour, making oxygen exposure relevant throughout manufacturing, filling and packaging.

Softgels provide part of the protection, but should not automatically be considered the complete barrier system.

For highly oxidation-sensitive products, both the oxygen barrier of the primary container and oxygen within the package headspace may therefore be relevant.

PROBIOTICS – MOISTURE CAN DETERMINE SURVIVAL

For probiotics, the objective is to maintain the required viability of living microorganisms throughout shelf life.

Moisture can be particularly damaging, while oxygen sensitivity may also be relevant depending on the strains involved.

Strong moisture management is therefore often important. HDPE can be an attractive starting point because of its strong moisture barrier, potentially combined with a desiccant depending on the product and required shelf life.

BOTANICAL EXTRACTS – COMPLEX INGREDIENTS REQUIRE INDIVIDUAL EVALUATION

Botanical extracts are highly diverse and may contain polyphenols, carotenoids, essential oils and numerous other compounds.

Depending on the extract, oxidation, moisture, light or temperature may affect stability. Curcumin and carotenoid-containing formulations, for example, illustrate why light exposure may be relevant.

There is therefore no universal packaging rule for botanical products. The specific extract, formulation and stability data should determine the required protection.

OTHER COMMON ACTIVE INGREDIENTS

The same principle applies to many other healthcare ingredients.

Coenzyme Q10 can be sensitive to light and oxidation. **Amino acids** vary considerably in stability. **Enzymes** can be sensitive to moisture and temperature, while **proteins and peptides** may introduce additional sensitivity to moisture, oxidation and environmental conditions.

The objective is not to create one packaging rule for every ingredient.

It is to identify potential stability risks as early as possible.

FROM INGREDIENT TO DOSAGE FORM

A sensitive ingredient does not necessarily mean that the packaging must provide all the protection.

The formulation and dosage form also play important roles.

Tablet excipients and coatings can contribute to stability. Gelatin and HPMC capsules have different moisture characteristics. Softgels can protect oils and fat-soluble ingredients, while powders may be particularly vulnerable to moisture uptake or oxidation because of their exposed surface area.

The dosage form and the package should therefore be considered as parts of the same protection system.

BUT WHAT IF YOU DO NOT KNOW WHAT YOUR PRODUCT REQUIRES?

Ingredient knowledge provides an excellent starting point – but not necessarily the final answer.

Once ingredients have been combined into a finished formulation, its stability characteristics may differ significantly from those of the individual components.

So what if you do not know how sensitive the finished product is?

Then it should be measured.

Analytical and stability testing can determine how a product responds to moisture, oxygen, light and temperature, moving the packaging discussion from assumptions towards measurable requirements.

MOISTURE SENSITIVITY AND CRITICAL-MOISTURE TESTING

For tablets, capsules and powders, moisture is often one of the first areas to investigate.

Dynamic Vapour Sorption (DVS) can measure how much moisture a product absorbs or releases at different relative humidity levels.

Critical-moisture testing, sometimes referred to as Moisture Critical Threshold (MCT/MCTR) testing, can help establish the moisture conditions at which meaningful product changes begin to occur.

These may include loss of potency, changes in tablet hardness, increased friability, sticking or capsule deformation.

Instead of simply saying:

“This product is moisture-sensitive,”

we can ask:

“How much moisture can this product tolerate during its intended shelf life?”

That is a far stronger basis for packaging development.

OXIDATION AND OXYGEN-SENSITIVITY TESTING

Products suspected of oxidation sensitivity can be exposed to controlled oxidative conditions and analysed for changes in active ingredient concentration, degradation products, colour, odour or other relevant parameters.

For oils and fatty-acid products, specific oxidation measurements may also be relevant.

The objective is to establish whether oxygen exposure is likely to limit shelf life and therefore how much oxygen protection the packaging system must provide.

PHOTOSTABILITY TESTING

Potentially photosensitive products can be exposed to controlled light conditions and compared with protected samples.

This becomes particularly relevant when transparent packaging is being considered.

If testing demonstrates significant light-related degradation, clear PET may need to be replaced by coloured or opaque PET or light-protective glass.

ACCELERATED AND REAL-TIME STABILITY TESTING

Ultimately, the complete product and packaging system should be evaluated together.

Accelerated stability studies use controlled elevated temperature and humidity conditions to reveal potential degradation mechanisms earlier, while real-time studies evaluate the product under its intended storage conditions over time.

Relevant parameters may include potency, moisture content, dissolution, tablet hardness, capsule integrity, appearance, colour, odour and microbiological performance.

The objective is to demonstrate that the **product and packaging system together** provide the required stability throughout the intended shelf life.

FROM PRODUCT DATA TO PACKAGING REQUIREMENTS

This is where analytical science and packaging engineering meet.

If testing demonstrates low moisture tolerance, strong moisture protection becomes important. If oxidation is the dominant degradation mechanism, oxygen barrier, headspace management or oxygen scavenging may become relevant. If light is the primary risk, transparency may need to be sacrificed for protection.

The purpose of testing is therefore not simply to establish whether a product is stable.

It is to understand **what makes it unstable and how much protection it requires.**

At Berlin Packaging, this information becomes the technical starting point for evaluating the complete packaging system.

FROM PRODUCT REQUIREMENTS TO PACKAGING MATERIAL

Once the product requirements are understood, we can define the required packaging barrier.

For rigid healthcare bottles and containers, three materials are particularly relevant: **HDPE, PET and glass.**

HDPE

HDPE provides excellent moisture barrier performance and is widely used for tablets, capsules and powders.

It is often a logical starting point where moisture is the primary risk. Its oxygen barrier is more moderate, meaning highly oxidation-sensitive formulations may require additional protection.

PET

PET provides better oxygen barrier performance than HDPE and combines this with clarity and strong shelf appeal.

It can be attractive where oxygen protection is important and moisture sensitivity is less critical. However, clear PET provides limited light protection, so photosensitive products may require coloured or opaque solutions.

GLASS

Glass provides an almost impermeable barrier to oxygen and moisture and is chemically inert for many healthcare applications.

Amber glass can additionally provide significant light protection.

Glass therefore offers a strong platform for sensitive formulations, although weight, transportation cost and breakage risk must be considered.

ACTIVE PACKAGING MAY COMPLETE THE SYSTEM

Bottle material is only one component of the packaging system.

Desiccants can support moisture control, while oxygen scavengers may provide additional protection against oxidation.

Closure performance, induction sealing, headspace and filling conditions can also influence actual package performance.

At Berlin Packaging, we therefore evaluate the **complete packaging system**, rather than the bottle material in isolation.

A PRACTICAL INGREDIENT-TO-PACKAGING FRAMEWORK

When beginning a healthcare packaging project, six questions can help establish the direction:

1. **What are the active ingredients?**
2. **Are they sensitive to moisture, oxygen or light?**
3. **How does the formulation and dosage form influence that sensitivity?**
4. **Do we know the sensitivity of the finished product – or should it be tested?**
5. **What barrier performance is required for the intended shelf life?**
6. **Which combination of HDPE, PET or glass, closure and active packaging can provide it?**

The process becomes:

Know the ingredient → Understand the sensitivity → Understand the dosage form → Measure what you do not know → Define the barrier → Select the packaging → Validate the system

CONCLUSION

Healthcare packaging selection should not begin with a bottle catalogue.

It should begin with the product – and often with the active ingredients themselves.

Knowing that a formulation contains an oxidation-sensitive vitamin, a hygroscopic ingredient, a photosensitive botanical extract or an oxidation-sensitive oil gives us an important early indication of what protection may be required.

But ingredient knowledge is only the starting point.

The finished formulation may behave differently. When its sensitivity is not sufficiently understood, **testing can replace assumptions with data.**

That information can then be translated into meaningful packaging requirements and ultimately into the appropriate combination of HDPE, PET or glass, closure and active packaging.

At Berlin Packaging, we see packaging development as a process connecting **ingredient science, formulation, dosage form, analytical testing, packaging engineering and stability validation.**

The package is the final physical barrier surrounding the product.

But the decision about that package should start much earlier.

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