Characteristics of rubber used in pharmaceuticals

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Executive summary
Rubber materials are widely used in systems used to manufacture, package and deliver pharmaceutical products. While the rubber material's nature and composition gives it its necessary and desirable performance characteristics, these material properties can have important and potentially detrimental consequences for the pharmaceutical product.

Interactions between these materials and the pharmaceutical products they contact are well known and documented and can result in a change in the product's composition, which may adversely affect product safety (e.g., the product produces an unanticipated and adverse user response) and/or efficacy (e.g., the product performs in a manner inconsistent with its labeling and indication).

Therefore, rubber materials used in pharmaceutical products must be evaluated to determine what material components can, and do, migrate from the materials and accumulate in the pharmaceutical product, as it is through the presence and actions of such substances that product safety and/or efficacy may be compromised.

The characterization of materials for their extractables (substances that can migrate) and of products for their leachables (substances that do accumulate) is a necessity and complex task—requirement, registration and manufacturing as well as distribution and therapeutic products. This manuscript provides a general overview of the extractables and leachables issues associated with materials used in therapeutic products.

Extractables and leachables: General concepts
As noted previously, the migration of an entity out of a system results in the accumulation of an entity in the pharmaceutical product. Thus the interaction between a system and a product can be assessed by considering either those substances present in the packaging which could migrate from the packaging or those substances derived from the packaging, that are present in the product. Although these two sets of substances may be closely related (Fig. 1), there can be clear differences between them, and thus the terms extractables and leachables were adopted to reflect the populations and emphasize their differences. The rigorous definitions of these two terms follow:
- Extractables: Those substances that are present in the therapeutic product because of its contact with a material, component, system, etc.
- Leachables: Those substances that are present in the material, component, system, etc, that can be extracted from that matrix by a solvent.

On the surface it seems logical that extracting rubber but rather are imparted to the rubber material's nature and composition gives it its necessary and desirable characteristics, to the pharmaceutical product. However, it is far easier to determine if a sample contains a known extractable than to determine if the sample contains "unknown" compounds.

Thus, the extractables profile of the system establishes what the probable identity of the extractables is, what is actually in the product that produces an unanticipated and adverse user response) and/or efficacy (e.g., the product performs in a manner inconsistent with its labeling and indication).

The guidance goes on to establish four aspects of suitability for use:
- Compatibility (that the product and container closure "will not interact sufficiently to cause unacceptable changes in the quality of either the dosage form or the packaging component")
- Performance (that the container closure system "functions in a manner for which it was designed")
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The considerable analytical challenge is "finding a needle in the haystack when you don't even know what the needle looks like" is greatly simplified if one is given the probable identity of the needle.

In the case of leachables testing, this means that it is far easier to determine if a sample contains a known extractable than to determine if the sample contains "unknown" compounds.

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Rubber

Continued from page 15

reacted with a number of chemical agents or additives (e.g., vulcanizing agents, accelerators, activators, plasticizers, plant oils, fillers, and antioxi-
dants, lubricants, see Table II) under harsh conditions of high temperature and pressure.

These substances, their impurities and their processing-induced reaction or decomposition products are all potential extractables.

The more commonly utilized classes of additives are considered in greater detail as follows.

Curing and vulcanizing agents: Natural rubber and synthetic analogs are often processed (e.g., cured and/or vulcanized) to obtain a material with the required physical and chemical properties.

These chemical agents, which typically gain in either sulfur or peroxide, react with active sites along the polymer chain to produce cross-linking.

The processes of vulcanization and/or curing may be facilitated by accelerators (such as gumminol, thiazoles, thio urams and thio dicarbamates) and/or activators (such as a metal oxide or fatty acid).

Antioxidants: Rubber articles are exposed to oxidation, flex, fatigue, ozone and light during their shelf-life. Additionally, many rubber parts are sterilized by gamma irradiation prior to use in pharmaceutical applications.

To improve their durability, they have to be protected by these additives.

For example, the oxidation of rubber can be considerably reduced by the addition of antioxidants, chemicals that destroy or scavenge free radicals before they have opportunity to react with rubber chains.

The origins of degradation in polymers are radical species such as: R • (alkyl radical) RO • (alkoxy radical) ROOH (hydroperoxide) R=OH (alcohol)

Fillers, such as metal silicates, silica, calcium carbonate and carbon black, are present in many rubber formulations. These additives can reduce the hardness and moisture sorption/desorption.

Light stabilizers are commonly used to protect elastomers from sunlight as well as artificial lighting. Many of these chemicals include benzenophenones, benzotriazoles, or triazines. This topic will be discussed in greater detail later.

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Use of antioxidants in pharmaceutical systems

The use of elastomers in the medical industry is nearly as old as the rubber industry itself. The potential utility of elastomers as components of packaging and delivery devices was recognized shortly after the discovery of the vulcanization process.

The unique properties of processed rubber, including elasticity, penetrability, resilience, ability to act as a gas/vap or barrier and general chemical compatibility were the driving force behind its ready adoption in early 21st century pharmaceutical applications (primarily as closures for glass vials). In fact, this is the case antecedents to today’s medical devices and pharmaceutical products.

Table II. Additives used in rubber formulations.

The dual requirements of functionali ty and suitability are, to some extent, inherently mutually exclusive, and thus there is a limited amount of "wiggle room" in the composition and processing design space that defines a viable product.

On the other hand, pharmaceutical products, especially biopharmaceuticals, are becoming more compositionally complex and "sensitive" to perturbations re

The authors

Daniel L. Norwood is a distinguished research fellow in the Analytical Sciences Department at Baxter Healthcare Corp. In this role, he works with a team of analytical chemists who are responsible for the development, validation and application of diverse analytical strategies and methods for the discovery, identification and quantification of trace constituents in pharmaceutical relevant solutions and samples.

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Michael Ruberto is the president of Material Needs Consulting LLC, which provides consulting services to manage the development and commercialization of medical devices and packaging, with a special emphasis on material selection, extractables and leachables, and supply chain management. Ruberto also runs a company that is employed by U.S. Specialty Chemicals for 15 years.

Frans DeGrazio has been in the pharmaceutical packaging industry for 25 years with expertise in delivery of injectable drug products. In 2006 he moved into his current role as vice president of marketing and strategic business development at West Pharmaceutical Services.

Jim Caster is a senior principal research scientist at Lanthel Medical Imaging, formerly Bristol-Myers Squibb Medical. He is world renowned for more than 16 years experience in the pharmaceutical industry. He has also worked for more than 10 years at DuPont in the Medical Products and the Agriculture Crop Protection units as a principal research scientist.

John Wong, senior staff scientist with ExxonMobil Chemical Europe, joined the company in 1987 and was involved in various application development on polymers and elastomers. He is currently the technical coordinator of butyl polymers in pharmaceutical stoppers and seal applications.

Dennis Jenke is a principal scientist in the Technology Resources Division of Baxter Healthcare Corp. In this role, he works with a team of analytical chemistry professionals who are responsible for the development, validation and application of diverse analytical strategies and methods for the discovery, identification and quantification of trace constituents in pharmaceutical relevant solutions and samples.

Table II. Additives used in rubber formulations.

<table>
<thead>
<tr>
<th>Function of Additive</th>
<th>Type of Additives to Perform That Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintain or Enhance Polymer Property</td>
<td>Polyolefin and/or Organophosphite Antioxidants, Antioxidants</td>
</tr>
<tr>
<td>Prevent Oxidation and Aging</td>
<td>Plastics, Plasticizers, Antioxidants/Curing Agents, Fillers</td>
</tr>
<tr>
<td>Protect from Environmental Stress</td>
<td>UV Absorbers, Ant Foaming Agents, Optical Brighteners, Light Stabilizers, Slip Agents</td>
</tr>
<tr>
<td>Provide Desired Product Property</td>
<td>Antioxidants, Antimicrobial Agents, Colorants</td>
</tr>
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</table>

Rubber poisons (such as copper, iron, cobalt, nickel and other transition met
related to material interactions. The juxtaposition of these two trends means that rubber/product interactions are still an important product design consideration and constraint.

This observation is supported by recent reported adverse events that have been associated with rubber/product interactions. For example, one of the most widely documented instances of an unanticipated incompatibility between a rubber component of a container closure system and a protein drug product is that of Eprex (epoetinum alfa) and its pre-filled syringe packaging system.26,27

At some point in its product lifetime (ca. 1998), Eprex, a product of recombinant human erythropoietin, was reformulated with polysorbate 80, which replaced human serum albumin as a formulation stabilizer. Shortly after this change, the incidence of anti-body mediated pure red cell aplasia (PCRA) with Eprex use by chronic renal failure patients increased. The cause of PCRA was directly linked to the formation of neutralizing antibodies to both recombinant and endogenous erythropoietin in patients administered Eprex. A considerable, cross-functional technical effort was undertaken to establish the root cause of this phenomenon. One potential root cause involved leached substances. The presence of previously unidentified leachables was suggested as new peaks in the tryptic map of Eprex. Leaching studies indicated that the polysorbate 80 extracted low levels of vulnerizing agents (and related sub- stances) from the uncoated rubber components of the pre-filled syringe.

This leaching issue was addressed by replacing the rubber components with components coated with a fluoropolymer.

See Rubber, page 18

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As the fluoropolymer is an effective barrier to migration, the leaching of the rubber's components was greatly reduced. Since the conversion from the uncoated to the coated components, the incidence of PRCA has returned to the baseline rate seen for all marketed epoetin products. This is strong circumstantial evidence that leaching of the vulcanizing agent was, in fact, the root cause of the observed effect.

Orally inhaled and nasal drug products: an example of extractables and leachables issues

Orally inhaled and nasal drug products (OINDP) are a drug product class used for the treatment of asthma, chronic obstructive pulmonary diseases (COPD), and systemic conditions such as diabetes. OINDP include metered dose inhalers (MDIs), dry powder inhalers (DPIs), nasal sprays, inhalation solutions and inhalation sprays.

OINDP are unique among drug product types in that the container closure system is an integral part of the drug product and critical for drug product performance. Container closure systems can include rubber, plastic, metal and other components.

Rubber components are most often used as seals, especially in metered dose inhalers (Fig. 2), which include an organic propellant under pressure as part of the formulation.

Because rubber and plastic incorporate chemical additives and processing aids and metal components often have organic residues on their surfaces, the potential exists for leaching of these chemicals from the components into the formulation.

The degree of regulatory concern regarding organic leachables in OINDP is summarized in Table 1, which is adapted from the FDA’s ‘Packaging Guidance.’ In Table 1, the ‘Likelihood of Packaging Component-Dosage Form Interaction’ (e.g. the likelihood of leaching) is linked with the ‘Degree of Concern’ associated with the Route of Administration. The inhalation route of administration is of high concern because:

- The patient population is sensitive and compromised. OINDP patients include individuals with asthma and various COPD (chronic obstructive pulmonary diseases, such as chronic bronchitis and emphysema) who by definition have compromised lung function and can show increased sensitivity to irritants.
- Paradoxical bronchospasm is an issue. Paradoxical bronchospasm is a relatively rare event in which a medicine prescribed to treat bronchospasm (a sudden narrowing of the airway, as in an asthma attack) or the underlying condition, has the effect of inducing bronchospasm.
- Paradoxical bronchospasm is a potentially life threatening event.

Although the causes of paradoxical bronchospasm are not well understood, it is advisable to reduce to the extent practical the potential irritant.

- OINDP tend to be for chronic administration, and therefore long-term use. OINDP are designed for the treatment of asthma, COPD and other systemic disease conditions such as diabetes. It is therefore likely that patients will take OINDP for many years if not decades.

Additionally, because MDI drug products include organic solvents under pressure in direct contact with rubber and plastic container closure system components, there is a high likelihood for interaction and leaching.

Because of this high level of concern, two specific guidance documents dealing with OINDP were issued by the FDA, one of which is related to ‘Nasal Spray and Inhalation Solution, Suspension and Spray Drug Products’ and the other (still at the time of this writing in draft form) related to ‘Metered Dose Inhaler and Dry Powder Inhaler Drug Products.’ These guidance documents, along with the ‘Packaging Guidance,’ describe what is generally expected for regulatory interactions related to inhaled drug products. Specifically, for MDI drug products the guidance suggests:

- Exhalation aerosol formulations include organic liquids as the propelants or the vehicle (e.g. chlorofluorocarbons, alcohols, etc.) and potential leaching of compounds from the elastomeric and plastic components of the container and closure systems. The formulation is a serious concern that should be addressed.
- Therefore, the composition and quality of the materials used in the manufacture of the container and closure system components should be carefully selected.

For safety considerations, materials should be chosen that minimize or eliminate leaching without compromising the integrity or the performance of the drug product.

The guidance says:

- “Identity and concentration profiles of the leachables in the drug product or placebo formulation (e.g. drug product formulation without drug substance) should be determined through the end of the drug product’s shelf life and correlated, if possible, with the extractables and leachables of the container and closure system components determined under the various control extraction study conditions.”

- To increase efficiency in the pharmaceutical development process, and to increase the likelihood of earlier regulatory approvals for new inhalation drug products, the developers of inhalation drug products desired even greater clarification regarding the regulatory requirements for extractables/leachables testing, qualification and control.

- In 2001, a Leachables and Extractables Working Group was formed by the Product Quality Research Institute to address the issue of inhalation safety qualification thresholds in inhalation drug products.

Based on a developed hypothesis and step-wise investigative plan, which included both literature investigations and laboratory work, the PQRI L&E Working Group produced a ‘Recommendation Document’ in 2006 which was submitted to the FDA.

The PQRI recommendations include two safety thresholds for leachables in inhalation drug products: ‘Qualification Threshold’ (QT) at 5 µg/day total daily intake for an individual organic leachable, and the ‘Safety Concern Threshold’ (SCT) at 0.15 µg/day total daily intake for an individual organic leachable.

The qualification threshold is defined as “the threshold below which a leachable is not considered for safety qualification (toxicological assessments) unless the leachable presents structure activity relationship concerns,” whereas the concern threshold is defined as “the threshold below which a leachable would have a dose so low as to present negligible safety concerns from carcinogenic and non-carcinogenic toxic effects.”

- The threshold at or above which a chemical should begin to identify a particular leachable and/ or extractable and report it for potential toxicological assessment, was defined as the ‘Analytical Evaluation Threshold,’ which is derived from the concern threshold with consideration of an individual drug product’s dosing requirements.

It is noted that the safety thresholds do not apply to the so-called “special case” compounds and compound classes (PAHs, N-nitrosamines, and 2-mercaptoethanol), which are deemed by the regulatory authorities to have special safety concern and therefore should be evaluated and controlled with technology-based thresholds.

The PQRI recommendations also included “Best Practices” for inhalation drug product development with regard to extractables and leachables.

The best practice recommendations cover the areas of selection of components, controls, leachables, and leachables testing. Both the safety thresholds and best practices recommendations have been independently reported in the scientific literature.

Developments in elastomers used in pharmaceutical applications

The ultimate objective of having cost effective, broadly applicable, functional and suitable pharmaceutical rubber components has only been partially realized, ongoing developments and future innovations in rubber composition, rubber processing and rubber utilization have the potential to close the gap between the utopia of tomorrow and the reality of today.

Vendors of rubber materials and products used in pharmaceutical applications have been actively engaged in addressing extractables and leachables issues.

One such example is brominated isobutylene-parylene terephthalamide (BILMSTM) has been reported to be a very clean material that can be Vulcanized effectively by a low level of clean curatives.

The use of coated rubber parts (e.g., rubber parts coated with a migration barrier such as polytetrafluoroethylene) in pharmaceutical applications is increasing.

Another area of increased vendor participation is in the area of processing extractables information to potential users of rubber materials.

An example of the vendor’s increasing willingness to provide such information is the VeriSure product line of rubber materials.

VeriSure products are certified on a lot-to-lot basis for extractables and the individual lots are supported by comprehensive extractables documentation including an extractable “finger print” and an extractables specification.

The aforementioned advances in the strategies for designing, performing and interpreting extractables and leachables safety assessments, in the composition of the materials themselves and in the level of vendor participation in the assessment process are further augmented in advances in the tactics (e.g., analytical approaches) utilized in the various facets of the E&L assessment.

The combined impact of all these advances is one that is characterized by effective, efficient and timely product development, registration, marketing and stewardship, supported by the principles of good science and Quality by Design.

Acknowledgements

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The individual authors wish to ac-
Elastocon TPE Technologies Inc. has published a brochure for its full line of custom and standard SEBS and non-SEBS series of thermoplastic elastomers, thermoplastic olefins and machine-side compounding solutions. The literature is enhanced with a variety of end-use product application photos. For a copy of the brochure, call 888-644-8732 or visit www.elastocon.com.

ExxonMobil Chemical Co. has introduced a high-flow thermoplastic vulcanize for automotive interiors. Santoprene TPV M350 can be processed using two components, a hot melt and crosslinking with molding onto a rigid polypropylene substrate to produce an unfoamed structure that does not indent. Also colorable, Santoprene TPV M350 offers low and stable gloss level, high scratch and mar resistance, good abrasion and chemical resistance, low fogging and odor emission, the company said.

For more information, call 281-870-6007 or visit www.evonichemical.com.

3M Co. has introduced a high-task electrical insulating tape for hard-to-hold applications. 3M Electrical Tape 441T is a polyester composite insulating tape with a durable backing providing a tough, puncture-resistant protective layer, the firm said. Specific applications include stick-wound coils/transformers and bobbin-wound coils for banding, anchoring, insulating and protecting start wires, leads, terminal strips, insulation strips, insulation paper, end turns and connections in motors and transformers, 3M said.

Visit www.3M.com/electrical or call 800-476-8381 for details.

Sartomer Co. has come out with improved retarding technology for the company’s crosslinking coagents. The retarding systems are less volatile, odorless and persist in the compound even at high processing temperatures, the company said. Sartomer products using the proprietary retarding packages are designated with an R.

For details, call 610-363-4100 or visit www.sartomer.com.

GLS Corp. has introduced halogen-free, flame retardant thermoplastic elastomers that provide an alternative to traditional flexible vinyl jacketing and insulation for consumer electronics applications. GLS’ OnFlex TPE materials comprise five groups of high-performance compounds. All grades are made without the use of halogenated flame retardants and do not contain phthalates, GLS said.

Visit www.glscorporation.com or call 800-457-8777 for more information.

D&M N.V. has introduced Keltan 1200A, a ultra-low viscosity EPDM for the petroleum additives market or processing additive for rubber applications. D&M said key processing benefits include excellent wetting properties for filters and fillers and improved adhesion in rubber compounds.

For information, visit www.dsm.com.

B&H Tool Co. has added to its line of plastic extrusion tooling for cable, hose and profile products. Included are: the Wedge Ring Remover, which enables operators to instantly pop out the wedge ring after each extrusion run; the Core Tube Remover that allows for removal of the core tube from the front end of the crosshead without damaging the front end, and a striping attachment, enabling the co-extrusion of a single, dual or triple strip, B&H said.

Bluestar Silicones USA Corp. has come out with Silcolese Poly 366, a solventless silicone polymer that offers a flat release coating system for liners and lami-nators. Designed to be used with Silcolese Optima se- ries technology, the company said the multifunctional polymer can be customized for fast, low-temperature cure or platinum formulation reduction.

For more information, call 866-474-6342 or visit www.bluestarsilicones.com.

Dr. Boy GmbH & Co. KG. has introduced the BOY XS, a compact injection molding machine with a clamping force of 1000kN. The machine is also available as an insert-molding machine with vertically arranged clamping and injection units, called the BOY XS V. The two models are suited for automation solutions from granules to the

Gummi, Kunststoffe, Lacke & Verpackungen (Chair), “Safety Thresholds and Best Practices For Extractables and Leachables in Orally Inhaled and

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 finished and packaged molded part, the company said.

Visit www.dr-boy.de for more information.

Rubber

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theorists in those areas, making it a leader in the market. It has been in operation since 1962, said IAC Chairman Wilbur L. Ross.

IAC bought Stankiewicz’s nine plants in Germany, Belgium, Poland and the Czech Republic for an undisclosed amount. The deal is expected to be completed by early to mid-July, at which time Stankiewicz will emerge from insolvency. The plants generate about $208 million in annual sales, IAC said.

The company’s two U.S. factories, one in Spartanburg, S.C., the other in Vance, Ala., and its factory in Sauzet, France, are not part of the deal.

The Stankiewicz facilities will be absorbed into IAC’s European business unit, which is made up of operations once owned by U.S. suppliers Lear Corp., Vis- tecon Corp. and Collins & Aikman Corp.

By Douglas Bolduc

KREFELD, Germany—International Automotive Components Group has expanded its global automotive car- pet and acoustic parts business by purchasing key customers such as BMW AG and Daimler A.G. provided the 64-year-old company unspecified support to prevent disruption of their assembly lines.

IAC purchased pieces of supplier Stankiewicz

Rubber

IAC purchased pieces of supplier Stankiewicz

KREFELD, Germany—International Automotive Components Group has expanded its global automotive carpet and acoustic parts business by purchasing key customers such as BMW AG and Daimler A.G. provided the 64-year-old company unspecified support to prevent disruption of their assembly lines.