



## TECHNICAL BULLETIN

# THE IMPORTANCE OF DRUG SPECIFICATIONS

Molecular weight and sulfation patterns of glycosaminoglycans in animal health

Veterinary Medical Affairs, American Regent, Inc.

### Key points

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## Why are drug specifications important?

Specifications are critical and establish the set of criteria to which a drug substance or drug product must adhere in order to be considered acceptable for its labeled use. An established set of drug specifications are necessary for accurate replication and consistency in manufacturing. The specifications are proposed and justified by a manufacturer and approved by the United States Food and Drug Administration Center for Veterinary Medicine (FDA-CVM) as conditions of animal drug approval.<sup>1</sup>

A drug specification is a quality standard. It establishes the benchmark to which the product must conform to be considered acceptable for the manufacture of the drug. Specifications include a list of tests with appropriate acceptance criteria, including limits and ranges as well as references to analytical procedures. For pharmaceuticals in the United States, these are all part of FDA drug approval to ensure drug consistency for the indicated use and administration. **This is not a requirement of veterinary medical devices or of animal nutraceuticals/"supplements."**<sup>2, 5</sup>

## Glycosaminoglycans in animal health

Glycosaminoglycans (GAGs) are large linear polysaccharides constructed of repeating disaccharide units with the primary unit configurations generally consisting of a 6-carbon amino sugar (either glucosamine or galactosamine) and a 6-carbon (sugar) -uronic acid (glucuronic acid) connected via a glycosidic bond.<sup>9</sup>



There are four primary groups of GAGs classified based on their core disaccharide units. These include heparin/heparan sulfate, chondroitin sulfate/dermatan, keratan sulfate and hyaluronic acid. GAGs are available in a variety of equine joint products including nutraceuticals/“supplements,” medical devices and FDA-approved drugs.

### Examples of Glycosaminoglycans commonly found in joint products:

**Chondroitin Sulfate (CS)** = galactosamine + glucuronic acid + 1 sulfate group

**Hyaluronate (HA)** = glucosamine + glucuronic acid

**Polysulfated Glycosaminoglycan (PSGAG); synthetically modified GAG resulting in primary units = galactosamine + glucuronic acid + 2-3 added sulfate groups**  
(3-4 total sulfate groups per disaccharide unit)

**Polysulfated glycosaminoglycan (PSGAG) and hyaluronate sodium (HA) are the only GAGs currently available as FDA-approved animal drugs for the treatment of degenerative joint disease (DJD) or osteoarthritis (OA) in horses.** Hyaluronate sodium is available in an intravenous product indicated in the treatment of joint dysfunction of the carpus or fetlock

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**Animal medical device products or animal nutraceuticals/“supplements” are not generic versions of FDA-approved drugs and cannot be considered equivalent.<sup>7</sup>**

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in horses due to non-infectious synovitis associated with equine osteoarthritis.<sup>3</sup>

Adequan® i.m. (PSGAG) is the only FDA-approved PSGAG drug and is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses. PSGAG can help control the clinical signs and diminish the pathologic processes of DJD/OA in horses.<sup>4</sup>

The evidence to support the safety and efficacy of other GAG products used outside of their intended purpose to treat joint disease or OA has not been proven. Furthermore, veterinarians and animal owners have no way to know if the manufacturing process of these non-FDA approved products meets quality standards and consistency from batch to batch. Medical devices, regardless of the sterility or suggested method of

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administration (ex: intra-articular GAG lavage solutions or intramuscular chondroitin sulfate supplements) are not FDA-approved drugs and are often administered extra-label for the treatment of DJD or OA in horses although purpose-specific drugs are available.<sup>5,6</sup>

Animal medical device products or animal nutraceuticals/“supplements” are not generic versions of FDA-approved drugs and cannot be considered equivalent.<sup>7</sup>

Two characteristics of GAGs that play an important role in distribution and activity within the body are molecular weight and sulfation. The combination of molecular weight with the sulfation pattern influences a GAG’s interactions with the molecular environment.<sup>8,9</sup> Because of this, the PSGAG that comprises Adequan i.m. is manufactured according to specific parameters as part of approved drug specifications governing sulfation pattern and molecular weight. The result is a low molecular weight, highly sulfated molecule that easily crosses the synovial membrane.

GAG strand length, molecular weight and ionic charge associated with sulfation patterns can vary significantly for both those GAGs naturally occurring in tissues and those found in animal health products.



## The importance of GAG sulfation pattern and molecular weight

**Differentiations between high molecular weight (HMW) and low molecular weight (LMW) drugs have been demonstrated to have functional differences affecting activity and pharmacokinetic properties.**<sup>9,10,11</sup> For example, the effects and properties of hyaluronic acid are well known to be size dependent with HMW and LMW HA having different applications.<sup>12</sup>

**GAGs commonly found in animal health products can vary widely in their molecular weight.** Chondroitin sulfate (CS) is a GAG found in many animal



nutraceuticals/“supplements” and medical devices, which are sometimes confused for FDA-approved drug products. The molecular weight of CS differs based on the source (shark, porcine, bovine) and/or manufacturing process, and may range from **6-33 kDa (averaging over 15 kDa)**.<sup>13</sup> There are no chondroitin sulfate FDA-approved animal drugs so there is no requirement for adherence to any drug specifications.

Hyaluronic acid or hyaluronate sodium (HA) is a large **non-sulfated GAG** with a molecular weight generally ranging from **4 to >500 kDa**.<sup>10</sup> The molecular weight of

in FDA-approved drug products for systemic administration is required to meet drug specifications. It is typically a lower molecular weight than that of other HA products intended for local or topical application and much lower compared to the high molecular weight HA (reaching 6000-7000 kDa) found naturally in healthy joint fluid. This especially high molecular weight hyaluronic acid is responsible for imparting the characteristic viscous, lubricating quality of synovial fluid.<sup>10</sup>

The low molecular weight PSGAG in Adequan i.m., an FDA-approved drug product, is a semi-synthetic drug with a specified molecular weight range of 3-15 kDa.<sup>4</sup> The PSGAG found in medical device products have no requirement to set or meet the same specifications as the FDA-approved drug.

**Sulfation of GAGs also plays a unique role in the production of physiological effects**—too little may not produce the desired distribution or activity and too much can also result in altered or unintended effects. For example, antithrombotic effects have been associated with some over-sulphated GAGs.<sup>14,15</sup> Sulfation pattern influences ionic charge. This feature contributes to pharmacokinetics and binding of the drug to various proteins and cells. For these



the HA ingredient found in different animal health products can vary considerably depending on type of product and intended use. The sodium hyaluronate

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COMMON JOINT PRODUCT INGREDIENT(S)	MOLECULAR STRUCTURE
Chondroitin Sulfate [CS]	GAG, Disaccharide: Repeating pairs of 6-carbon sugars + glycosidic bond 1 sulfate group per disaccharide unit at either the 4- or 6-carbon location
Hyaluronate Sodium [HA] Hyaluronate Hyaluronic Acid	GAG, Disaccharide: Repeating pairs of 6-carbon sugars + glycosidic bond Usually a higher molecular weight than other GAGs No sulfate groups
Polysulfated Glycosaminoglycan [PSGAG]	GAG, Disaccharide: Repeating pairs of 6-carbon sugars + glycosidic bond 3-4 sulfate groups per disaccharide
Glucosamine [GLU] - not a GAG	Monosaccharide: Repeating pentose [5-carbon] sugar No sulfate groups
Pentosan Polysulfate [PPS] - not a GAG	Monosaccharide: Xylose hydrogen sulfate Polymers composed of repeating pentoses [5-carbon sugars] Plant derived - hemicellulose Semi-synthetic polysulfated xylan 2 sulfate groups per monosaccharide unit



reasons, setting sulfation specifications for sulfated GAG drugs is important.

Like molecular weight, the sulfation patterns for GAGs found in animal health products varies. Chondroitin sulfate found in animal medical device products and nutraceuticals/"supplements" is generally either chondroitin 4 sulfate or chondroitin 6 sulfate. Each of these has just one sulfate group attached to the galactosamine ring of each disaccharide unit (at either the 4 or 6 carbon location).



The PSGAG in the FDA-approved drug, Adequan® i.m., has 3-4 sulfate groups per disaccharide unit, added through a process of esterification. As described, specifications for molecular weight and sulfation are required for PSGAG drugs due to the influence of these parameters

on the interactions with the extracellular environment, including adhesive proteins and cytokines.<sup>13</sup> The absorption, distribution, metabolism and excretion following intramuscular injection of the low molecular weight PSGAG in Adequan i.m. has been well studied. PSGAG has been shown to inhibit certain catabolic enzymes which have increased activity in inflamed joints, and to enhance the activity of some anabolic enzymes.<sup>4,16</sup>

For example:<sup>16</sup>

- PSGAG has been shown to significantly inhibit serine proteinases, which have been demonstrated to play a role in the Interleukin-1 mediated degradation of cartilage proteoglycans and collagen.
- PSGAG is reported to be an inhibitor of Prostaglandin E2 (PGE2) synthesis. PGE2 has been shown to increase the loss of proteoglycan from cartilage.
- PSGAG has been reported to inhibit some catabolic enzymes such as elastase, stromelysin, metalloproteases, cathepsin B1, and hyaluronidases, which degrade collagen, proteoglycans and hyaluronic acid in degenerative joint disease.
- Anabolic effects studied include the ability of PSGAG to stimulate the synthesis of protein, collagen,

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COMMON NON-PHARMACEUTICAL GAG INGREDIENTS	MEDICAL DEVICE/"SUPPLEMENT" INDICATION(S)
<b>PSGAG*</b> polysulfated glycosaminoglycan	Topical wound dressing Post-surgical lavage
<b>HA*</b> hyaluronate sodium or hyaluronic acid	Topical wound dressing Post-surgical lavage
<b>CS</b> chondroitin sulfate	Performance, comfort, mobility Increase comfort and mobility
<b>PPS**†</b> pentosan polysulfate	Sterile lavage - urinary bladder

\*Exists in an equine pharmaceutical drug product and some non-drug products.

†Not a GAG.

proteoglycans and hyaluronic acid in various cells and tissues *in vitro*.

**PSGAG medical device products are not required to meet the same drug specifications, including those for molecular weight and sulfation as that found in Adequan® i.m.**

## What defines a drug?

In general, drugs have to undergo a burdensome FDA review and approval process unlike medical devices. For GAG products that are designed for another purpose and used extra-label as DJD or OA treatments, there is a lack of peer-reviewed clinical or research data. Additionally, specifications for the GAG ingredient may not be established or

consistent with that of a similar ingredient found in an FDA-approved drug.

Drugs are substances that target disease mechanisms to produce a physiological change and are intended to affect a structure or function in the body. A medical device is designed to diagnose, prevent, mitigate, treat, or cure disease or other condition but, unlike a drug, achieves its primary purpose by physical, structural or mechanical action and not through chemical or metabolic activity within the body.<sup>5</sup> However, medical devices may have secondary effects on biological or physiological processes. **This highlights the importance of following label directions and utilizing products as intended by the manufacturer.**



## Discussion

The FDA-CVM has established different regulatory requirements for animal drugs and medical devices based on their primary mechanism of action. Non-pharmaceutical GAG products should not be considered equivalent to an approved pharmaceutical product and have no requirement to meet drug specifications. Variations in chemical composition, including sulfation and molecular weight for similarly labeled GAG medical device or nutraceutical/"supplement" ingredients, could have implications if used extra- or off-label.<sup>17</sup>

A New Animal Drug (which refers to the original or pioneer product) and generic drugs must follow strict requirements set out by the FDA-CVM. This includes:

- √ Providing safety and efficacy data
- √ Following strict manufacturing protocols
- √ Conforming to approved drug specifications
- √ Providing marketing materials for FDA review
- √ Reporting adverse events
- √ Conducting ongoing testing of product for quality and stability

- √ FDA inspection of the approved manufacturing facilities

These are not required of compounded drugs, animal medical devices or nutraceutical/"supplement" products.<sup>1</sup>

## Additional Information

The American Association of Equine Practitioners (AAEP):<sup>18</sup>

"Medical devices are designed and manufactured for a specific use. These products may be useful tools to the equine practitioner for those intended purposes. Veterinarians should be aware that these products have not been evaluated to determine their suitability as a pharmaceutical by any regulatory agency and are not generic drugs. The final decision whether to use these products should be based upon what is in the best interest of the patient.

Regarding the use of injectable medical devices, AAEP encourages veterinarians to follow the guidelines provided in the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) regarding the extra-label use of pharmaceuticals which does not apply to medical devices. The FDA has considerable resource information available on medical devices and veterinarians are encouraged to review this material."

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## Additional guidance from the AAEP.

"A veterinarian considering use of a veterinary device as a pharmaceutical, should consider the following:

- The care and welfare of the animal should be foremost for all treatment decisions.
- The medical devices manufactured solely for use in veterinary medicine have not gone through any type of approval process, as such, there is no requirement for safety or efficacy evaluation.
- The manufacturing process of these devices is not required to meet specific, uniform standards. For example, there is no regulatory oversight process to assure quality control of purity, potency, stability and sterility.
- There are no mandatory requirements for reporting or cataloging an adverse event.
- If there are FDA-approved products available and formulated in the appropriate dosage for the disease



indication of the patient, those products should be used.<sup>18</sup>

- Veterinarians should inform clients when a medical device is used as a pharmaceutical.
- It is unethical for a veterinarian to promote or represent a medical device as equivalent to an approved pharmaceutical product.
- It is illegal for a manufacturer to promote or represent a medical device as a pharmaceutical."

## **Adequan® i.m. polysulfated glycosaminoglycan (PSGAG) solution 100 mg/mL**

**INDICATIONS** Adequan® i.m. is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

**IMPORTANT SAFETY INFORMATION** There are no known contraindications to the use of intramuscular Polysulfated Glycosaminoglycan (PSGAG). Studies have not been conducted to establish safety in breeding horses. **WARNING:** Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medications out of the reach of children.

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian. For additional safety information, please see full prescribing information at [adequan.com](http://adequan.com).



## The Basics About Regulation

**The Federal Pure Food and Drug Act of 1906** was the first law to regulate drugs to ensure safety and gave the FDA power to ensure drug safety by monitoring and regulating the manufacture and marketing of drugs.

**The Federal Food, Drug and Cosmetic Act of 1938 (FFDCA)** allows the FDA to ensure drug safety by monitoring and regulating the manufacture and marketing of drugs. Drugs must be labeled with accurate information including adverse effects. Only drugs considered safe by the FDA are approved for marketing.

**The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)** “permits veterinarians to prescribe extralabel uses of drugs only under certain conditions.” Under AMDUCA, any extralabel use of an approved new animal or human drug must be by order of a veterinarian within the context of a valid veterinarian-client-patient relationship (VCPR). Extralabel use must also comply with other provisions.<sup>19</sup>

**Extralabel** “Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses.” (21 CFR 530.3(a))

**“Off-label”** is a term commonly used in other countries and by physicians in the United States. It is also sometimes used in veterinary medicine, but the term has no legal or regulatory definition. (AVMA.org)

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**SINGLE DOSE**  
Solution 500 mg/5 mL  
For Intramuscular Use In Horses



**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION:** Each 5 milliliters of Adequan® i.m. contains 500 mg of Polysulfated Glycosaminoglycan (PSGAG) and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid added when necessary to adjust pH. Sodium Chloride may be added to adjust tonicity.

**PHARMACOLOGY:** Polysulfated Glycosaminoglycan is chemically similar to the glycosaminoglycans in articular cartilage matrix. PSGAG is a potent proteolytic enzyme inhibitor and diminishes or reverses the pathologic processes of traumatic or degenerative joint disease which result in a net loss of cartilage matrix components. PSGAG improves joint function by reducing synovial fluid protein levels and increasing synovial fluid hyaluronic acid concentration in traumatized equine carpal and hock joints.

**INDICATIONS:** Adequan® i.m. is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

**DOSAGE AND ADMINISTRATION:** The recommended dose of Adequan® i.m. in horses is 500 mg every 4 days for 28 days intramuscularly. The injection site must be thoroughly cleansed prior to injection. Do not mix Adequan® i.m. with other drugs or solvents.

**CONTRAINDICATIONS:** There are no known contraindications to the use of intramuscular Polysulfated Glycosaminoglycan.

**WARNINGS:** Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medications out of the reach of children.

**PRECAUTIONS:** The safe use of Adequan® i.m. in horses used for breeding purposes, during pregnancy, or in lactating mares has not been evaluated.

**ANIMAL SAFETY:** Toxicity studies were conducted in horses. Doses as high as 2,500 mg were administered intramuscularly to 6 horses twice a week for 12 weeks. This dosage is 5 times the recommended dosage and 3 times the recommended therapeutic regimen. Clinical observations revealed no soreness or swelling at the injection site or in the affected joint. No animal had any clinical or laboratory evidence of toxicity.

**STORAGE CONDITIONS:** Store at 20°-25°C (68°-77°F); (See USP Controlled Room Temperature). Discard unused portion.

Dispose of spent needles in accordance with all federal, state and local environmental laws.

**HOW SUPPLIED:** Adequan® i.m. solution, 500 mg/5 mL (100 mg/mL) in a 5 mL single dose glass vial.

NDC 10797-995-70      5 mL Single Dose Vials      Packaged 7 vials per box

AMERICAN REGENT, INC.  
ANIMAL HEALTH  
Shirley, NY 11967  
(1-888-354-4857)

Made in U.S.A.  
IN99501  
Rev. 9/2021  
MG #44455

Approved by FDA under NADA # 140-901



**MULTI-DOSE**  
Solution 100 mg/mL in a 50 mL Preserved Multi-Dose Vial  
For Intramuscular Use In Horses Only. Not for Intra-Articular Use.



**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION:** Each mL contains Polysulfated Glycosaminoglycan (PSGAG) 100 mg, Benzyl Alcohol 0.9% v/v as a preservative, and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid added when necessary to adjust pH. The solution is clear, colorless to slightly yellow.

**PHARMACOLOGY:** Polysulfated Glycosaminoglycan is chemically similar to the glycosaminoglycans in articular cartilage matrix. PSGAG is a potent proteolytic enzyme inhibitor and diminishes or reverses the pathologic processes of traumatic or degenerative joint disease which result in a net loss of cartilage matrix components. PSGAG improves joint function by reducing synovial fluid protein levels and increasing synovial fluid hyaluronic acid concentration in traumatized equine carpal and hock joints.

**INDICATIONS:** Adequan® i.m. Multi-Dose is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

**DOSAGE AND ADMINISTRATION:** Practice aseptic techniques in withdrawing each dose to decrease the possibility of post-injection bacterial infections. Adequately clean and disinfect the stopper prior to entry with a sterile needle and syringe. Use only sterile needles, and use each needle only once.

The vial stopper may be punctured a maximum of 10 times.

The recommended dose of Adequan® i.m. Multi-Dose in horses is 500 mg every 4 days for 28 days intramuscularly. The injection site must be thoroughly cleansed prior to injection. Do not mix Adequan® i.m. Multi-Dose with other drugs or solvents.

**CONTRAINDICATIONS:** There are no known contraindications to the use of intramuscular Polysulfated Glycosaminoglycan.

**WARNINGS:** Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medications out of the reach of children.

**PRECAUTIONS:** The safe use of Adequan® i.m. Multi-Dose in horses used for breeding purposes, during pregnancy, or in lactating mares has not been evaluated.

**SAFETY AND EFFICACY:** Safety and efficacy studies utilizing Adequan® i.m. Multi-Dose were not performed. Adequan® i.m. Multi-Dose was approved based on the conclusion that the safety and effectiveness of Adequan® i.m. Multi-Dose will not differ from that demonstrated for the original formulation of Adequan® i.m.

**ANIMAL SAFETY:** Animal Safety studies utilizing Adequan® i.m. Multi-Dose were not performed. Safety studies were conducted in horses using the single dose formulation. Doses as high as 2,500 mg were administered intramuscularly to 6 horses twice a week for 12 weeks. This dosage is 5 times the recommended dosage and 3 times the recommended therapeutic regimen. Clinical observations revealed no soreness or swelling at the injection site or in the affected joint. No animal had any clinical or laboratory evidence of toxicity.

**STORAGE CONDITIONS:** Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature). Avoid prolonged exposure to temperatures ≥ 40°C (104°F).

Use within 28 days of first puncture and puncture a maximum of 10 times. Dispose of spent needles in accordance with all federal, state and local environmental laws.

**HOW SUPPLIED:** Adequan® i.m. Multi-Dose solution, 5,000 mg/50 mL (100 mg/mL) in 50 mL multi-dose glass vials.

NDC 10797-959-01      50 mL Multi-Dose Vials      Packaged 1 vial per box

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