

CRODA | Pharma

SMART SCIENCE TO IMPROVE LIVES™



Veterinary formulation solutions

High purity excipients and adjuvant systems

www.crodapharma.com

Partnering to tackle your most challenging formulations

High purity excipients and adjuvant systems

Our excipient and formulation solutions enhance **palatability**, **efficacy**, **solubility** and **stability** of actives and formulations for livestock and companion animals.

We are passionate about enabling next generation small molecules and biologics, including veterinary vaccines.

High purity excipients



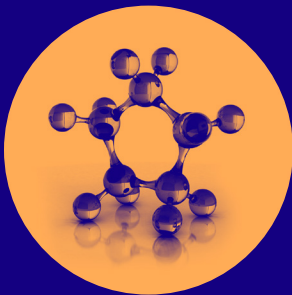
World-leading adjuvant systems



Innovative lipids



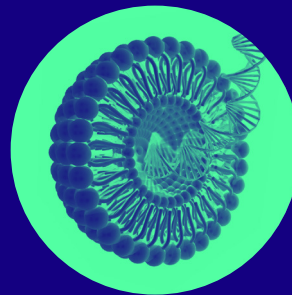
Empowering biologics delivery



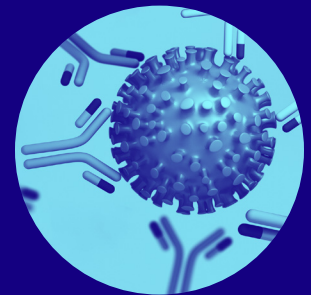
Small Molecule Delivery



Protein Delivery



Nucleic Acid Delivery



Adjuvant Systems

Discover our range

Our excipient portfolio is unparalleled in its purity and breadth, and we are passionate about developing innovative adjuvants for tomorrow's vaccines and providing GMP solutions for today.

- Permeation enhancers
- Vehicles/solvents
- Emulsifiers
- Barrier repair lipids
- Adjuvant systems
- Viral inactivators
- Bioprocessing aids

Small molecule pharmaceuticals



Biologics



Better
palatability



Enhanced
stability and
solubility



Improved
efficacy



Highest purity excipients

We specialise in developing tailored and high purity excipients and solutions for veterinary formulations.

Our exclusive range of Super Refined™ and highly purified excipients offers unparalleled breadth and purity for formulators. They have been designed to reduce the risk of product degradation and to improve chances for successful formulation development, thanks to their low peroxide, aldehyde and organic acid levels, absence of catalyst residues and low moisture content.

Our expertise addresses challenges in companion animals and livestock formulations, such as ingredients for controlled release oral dosage forms to overcome challenges on animal's gastrointestinal physiology and improved taste profile excipients to increase treatment adhesion. Croda's Super Refined range is excellent in solubilising and stabilising difficult-to-dissolve actives. Additionally, our range includes high purity permeation enhancers for topical veterinary formulations.

Research and GMP lipids

We are experts in the development and manufacture of research and GMP grade lipids for nucleic acid delivery. Discover more in our vaccine brochure.

Innovative and GMP adjuvants

Leveraging over 80 years of expertise in vaccine adjuvants, we are committed to manufacturing and supplying the GMP adjuvants needed today and developing the novel adjuvants of tomorrow.

Our industry-leading Quil-A™ is widely recognised in the vaccine industry as well as Alhydrogel™, and Adju-Phos™.

New adjuvants are also in development, continuing our offer for veterinary vaccines.

Partner with us

We collaborate directly with customers to optimise our products for your formulations, empowering you to develop the next generation of products.

Our expertise in high purity excipients and formulation enables us to employ Quality by Design (QbD) in our labs for effective development and optimisation.

Leveraging cutting edge technologies globally, we partner to formulate and evaluate your small molecule and biologic products to help improve bioavailability and other key parameters.

Working together, you will gain crucial insights into how the final formulation will perform using our products.

Contact our experts

To partner with us or enquire about further product information, such as monograph compliance, please contact your sales representative or email us at:

Europe, Middle East & Africa:

pharma.emea@croda.com

Latin America:

pharma.latam@croda.com

North America:

pharma.usa@croda.com

Asia Pacific:

pharma.asia@croda.com



Product name	Chemical description	Physical form	HLB	Monograph**					Routes/ applications*				Product description
				FDA IID*	Ph. Eur.	USP/NF	JP/JPE	ChP	Parenteral	Oral	Topical	Auricular/ ophthalmic/ nasal	
Permeation enhancers													
Cithrol™ GMO HP	Glycerol monooleate	Off-white solid	3.0	■	■					■	■		High purity lipid-based drug delivery excipient offering the potential for enhanced bioavailability of actives coupled with controlled drug release. It offers sustained drug release and greater active bioavailability for topical dosage forms.
Super Refined™ DEGEE	Diethylene glycol monoethyl ether	Liquid	16.0	■	■	■				■*	■	■	Super Refined DEGEE is ideal for use in topical applications to enhance the permeation of poorly water-soluble API's through various layers of the skin, thereby improving drug delivery. Only for veterinary health it can be used for parenteral applications according to EMA. No MRL (EU) (all ruminants and porcine).
Super Refined™ DMI	Dimethyl isosorbide	Clear, essentially colourless liquid		■								■	High purity liquid for use with poorly soluble hydrophilic actives. Enhances the formulation and API stability in transdermal delivery systems. Recommended topical usage levels of 5-10%.
Super Refined™ IPM	Isopropyl myristate	Colourless liquid	10.0	■	■	■	■					■	Highly purified grade of isopropyl myristate for use with sensitive active pharmaceutical ingredients or in applications where standard Crodamol IPM is not suitable.
Super Refined™ Lauryl Lactate	Lauryl lactate	Clear, colourless liquid	14.0	■								■	Highly purified alpha hydroxy acid (AHA) ester product. While occasionally used as a surfactant in an emulsion, typical applications for lauryl lactate include emolliency and penetration enhancement in topical formulations.
Super Refined™ Oleic Acid	Oleic acid	Clear, essentially colourless liquid	1.0	■	■	■	■			■	■	■	Highly purified oleic acid, used as a co-emulsifier in topical pharmaceutical formulations. Suitable as a penetration enhancer in transdermal products. In addition, it can be used to improve the bioavailability of poorly water soluble drugs. Recommended topical usage levels of 2-25%.
Super Refined™ Oleyl Alcohol	Oleyl alcohol	Clear, essentially colourless liquid	14.5	■	■	■						■	Highly purified permeation enhancer that promotes skin penetration by means of bilayer disruption and disordering. It assists the percutaneous absorption of water-soluble and oil-soluble drugs by means of partial leaching of the epidermal lipids. Recommended topical usage of 2-10%.
Super Refined™ Oleyl Oleate	Oleyl oleate	Colourless to pale yellow liquid	7.0	■		■	■					■	Highly purified grade of pharmaceutical oleyl oleate. A plant-derived light and non-greasy emollient.
Gel vehicles													
Crodabase™ SQ	Mineral oil (and) polyethylene blend	Smooth, oily, translucent gel		■								■	A soft, oily, translucent ointment base enabling topical formulations that are easy to apply and deliver a smooth skin feel. Excellent temperature stability (-15 to 60°C). Easy to use, suitable for cold processing and provides a superior alternative to petrolatum. Recommended topical usage levels of up to 100%.
Emulsifiers, solubilisers and dispersing agents													
Cithrol™ GMS 40 Pharma	Glycerol monostearate	Off-white solid	3.4	■		■				■	■	■	Non-ionic emulsifier, W/O and O/W emulsion stabiliser, dispersant and emollient used in oral and topical pharmaceutical preparations. Forms sustained release matrices. Recommended topical usage levels of 1-10%.
Crodasol™ CCMG 400	Caprylocaproyl polyoxyglycerides 8	Liquid	14.0	■	■	■							Mixture of caprylocaproyl macroglyglycerides that demonstrates amphiphilic characteristics and is primarily used in oral pharmaceutical applications. Due to its amphiphilic nature, it is ideal for use as a surfactant or co-solvent in SEDDS or SMEDDS. It can help solubilise poorly water-soluble APIs, thereby enhancing their bioavailability.
Crodasol™ HS HP	Polyoxyl 15 hydroxystearate	White to pale yellow waxy solid	15.0	■	■	■				■	■	■	Good surfactant for electrolyte products for companion animals. Good solubiliser for vitamins and vehicle for formulation with amino acids. Can be used in oral and injectable formulations.
Croduret™ 40 Pharma	PEG 40-45 hydrogenated castor oil	Off-white paste	13.0	■	■	■				■	■		Virtually tasteless solubiliser widely used for vitamins and a variety of oral formulations. Excellent solubiliser for vitamins A, E and D.
Etocas™ 35 Pharma	PEG 35 castor oil	Colourless liquid	12.7	■	■	■				■	■		Good surfactant for electrolyte products for companion animals. Good solubiliser for vitamins and vehicle for formulation with amino acids.
Span™ 20 HP	Sorbitan laurate	Pale yellow liquid	8.6	■	■	■	■			■	■		Span HP grades have reduced moisture levels, lower peroxide values and lower acid values. Spans are W/O emulsifiers and when used in combination with ethoxylated sorbitan esters (the Tween range) they contribute to the overall stability of O/W emulsions.
Super Refined™ CCMG 400	Caprylocaproyl polyoxyglycerides 8	Liquid	14.0	■	■	■							Super Refined version of Crodasol CCMG 400 Pharma.
Super Refined™ P35 Castor Oil	Polyoxyl 35 castor oil	Liquid	14.0	■	■	■	■			■	■	■	Super Refined version of Etocas 35 Pharma.
Super Refined™ Polysorbate 20	Polysorbate 20	Clear, essentially colourless liquid	16.7	■	■	■	■	■	■	■	■	■	Highest purity grade of Polysorbate 20 used to formulate oil-in-water emulsions for oral, topical or injectable formulations.
Synperonic™ PE/F 68 Pharma	Poloxamer 188	Flakes		■	■	■				■	■		Widely used for oral applications due to its defoaming properties. Functions well as an O/W emulsifier and as an effective solubiliser, wetting and defoaming agent. Frequently used in anti-bloat applications for cattle.
Synperonic™ PE/F 127 Pharma	Poloxamer 407	Flakes		■	■	■	■			■	■	■	High molecular weight (12000g/mol) and high polyethylene oxide content. Functions well as an O/W emulsifier and as an effective solubiliser. Often used in oral formulations to minimise taste impact as it does not have a bitter taste profile. Useful in ophthalmic applications as it is very mild and helps reduce irritation and infection.
Tween™ 20 HP	Polysorbate 20	Clear yellow liquid	16.7	■	■	■	■	■	■	■	■	■	Promote very stable O/W emulsion systems when used in association with the Span range. Good solubilisers for liposoluble actives. High Purity (HP) grades can be used to formulate water-in-oil emulsions for oral, topical and injectable formulations.
Tween™ 60 HP	Polysorbate 60	Yellow liquid/soft solid	14.9	■	■	■				■	■		

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For more information in our Lipid portfolio please get in touch.

Product name	Chemical description	Physical form	HLB	Monograph**					Routes/ applications*				Product description	
				FDA IID*	Ph. Eur.	USP/NF	JP/JPE	ChP	Parenteral	Oral	Topical	Auricular/ ophthalmic/ nasal		
Vehicle/solvents														
Crodamol™ CAP	Cetostearyl ethylhexanoate (and) isopropyl myristate	Colourless liquid	8.0									■		Branched chain ester with excellent spreading properties. Effective water repellent for pour-on applications. Required HLB value of 8. Recommended topical usage levels of 2-10%.
Crodamol™ EO Pharma	Ethyl oleate	Pale yellow liquid	11.0	■	■	■					■	■		Low viscosity solvent for lipophilic actives. Non-occlusive emollient with good spreading properties. Rapidly absorbed by body tissues. Dermal penetration enhancer. Required HLB value of 11. Recommended topical usage levels of 0.5-5%.
Crodamol™ GTCC Pharma	Caprylic capric medium chain triglyceride	Colourless liquid	10.0	■	■	■				■	■	■		Good emollient with excellent oxidative stability. Vehicle for anti-parasitic pour-on applications. Required HLB value of 10. Recommended topical usage levels of 0.5-20%.
Crodamol™ IPM Pharma	Isopropyl myristate	Colourless liquid	10.0	■	■	■	■					■	■	Solvent used in topical formulations to encourage rapid absorption on the skin. Presence of ester groups increase product spreadability in topical formulations for pour-on applications. Recommended topical usage levels of 0.5-5%.
Crodamol™ PC Pharma	Propylene glycol dicaprylocaprate	Colourless/very pale yellow liquid	8.0		■	■						■		Low viscosity solvent with good spreading properties. Good skin penetration enhancer to increase active absorption of pour-on formulations. Solubiliser and carrier for injection formulations. Vehicle for anti-parasitic pour-on and endectocide applications. Recommended topical usage levels of 2-10%.
Crodamol™ PMP	PPG 2 myristyl ether propionate	Colourless liquid	8.0									■		Rapidly absorbed solvent for lipophilic actives. Promotes good spreadability and is an excellent vehicle for pour-on applications. Recommended usage levels of 0.5-10%.
Super Refined™ Benzyl Alcohol	Benzyl alcohol	Liquid	12.9		■	■	■			■	■	■	■	High purity aromatic alcohol widely used in parenteral formulation and solubiliser in antimicrobial preservative in oral liquid formulations.
Super Refined™ Castor Oil	Castor oil	Clear, essentially colourless liquid	14.0	■	■	■	■	■		■	■	■	■	Highly purified triglyceride of fatty acids composed of ricinoleic acids, oleic acid, linoleic acid, palmitic acid and stearic acid. Commonly used in topical creams and ointments as well as in oral tablets and capsule formulations. May also be used in ophthalmic emulsions and as a solvent for intramuscular injections.
Super Refined™ Corn Oil	Corn oil	Clear, essentially colourless liquid	7.9	■	■	■				■	■	■		High purity corn-derived triglyceride that is primarily used in pharmaceutical formulations as a solvent and/or vehicle for intramuscular injections. It is also commonly used in oral dosage forms in tablets, capsules and suspensions.
Super Refined™ Cottonseed	Cottonseed oil	Clear, essentially colourless liquid	7.9	■		■				■	■	■		High purified cottonseed-derived triglyceride that can be used as a solvent and vehicle for injectables, as an emollient vehicle for other medications and orally as a mild cathartic. It can also be used in oral capsule dosage forms.
Super Refined™ GTCC	Caprylic capric medium chain triglyceride	Colourless liquid	10.0	■	■	■	■	■		■	■	■		Super Refined version of Crodamol GTCC Pharma.
Super Refined™ Olive Oil	Olive oil	Clear, essentially colourless liquid	7.7	■			■				■	■		Highly purified olive-derived triglyceride that can be used topically as an emollient and lubricant in emulsions, ointments, liniments, ophthalmic and otic preparations and oral capsules.
Super Refined™ Peanut Oil	Peanut oil	Clear, essentially colourless liquid	7.8	■	■	■				■	■	■		Highly purified peanut-derived triglyceride that is suitable for use as an excipient in pharmaceutical formulations, as a solvent for sustained-release intramuscular injections and as a vehicle for topical preparations, nasal drug delivery systems and controlled release injectables. In addition, it can be used in emulsions for nutritional applications.
Super Refined™ PEG 300	Polyethylene glycol 300	Colourless viscous liquid		■	■	■	■			■	■	■	■	Highly purified polyethylene glycol that can enhance API and overall formulation stability. Highly stable and non-irritating, ideal for ointment bases as they do not readily penetrate the skin. A wide array of uses in multiple dosage forms and can be used to enhance the aqueous solubility or dissolution characteristics of poorly soluble compounds.
Super Refined™ PEG 400	Polyethylene glycol 400	Colourless viscous liquid		■	■	■	■			■	■	■	■	
Super Refined™ PEG 600	Polyethylene glycol 600	Colourless viscous liquid		■	■	■	■			■	■	■	■	
Super Refined™ Propylene Glycol	Propylene glycol	Clear liquid	11.6	■		■	■	■		■	■	■	■	Highly purified grade of propylene glycol widely used in parenteral formulation and solubiliser or antimicrobial preservatives in oral liquid formulations.
Super Refined™ Safflower Oil	Safflower oil	Clear, essentially colourless liquid	7.7			■				■	■	■		Highly purified safflower-derived triglyceride that is rich in essential fatty acid linoleic acid. Odourless, light and quickly absorbed oil, widely used as an emollient in the treatment of dry skin and eczema.
Super Refined™ Sesame Oil	Sesame oil	Clear, essentially colourless liquid	7.8	■	■	■	■	■		■	■	■		Highly purified sesame-derived triglyceride that can be used as a solvent in the preparation of sustained-release intramuscular/subcutaneous injections of oil soluble actives. It is used in suspensions and emulsions, ointments and oral capsules. Its improved taste profile enables the formulation of more palatable oral liquid medicines.
Super Refined™ Soybean Oil	Soybean oil	Clear, essentially colourless liquid	7.7	■	■	■	■			■	■	■		Highly purified soy-derived triglyceride that can be used as a fat source in parenteral nutritional applications. Can be used as a vehicle for oral and intravenous drug administration and as an emollient in topical preparations.
Vet Pur™ Sesame Oil	Sesame oil	Yellow to pale-yellow liquid	7.8			■				■	■	■		Standard grade of USP sesame oil. Use as a vehicle or solvent in veterinary formulations such as parasiticides, hormones, antibiotics and anti-inflammatories. Compatible with components of injectable, topical (pour-on) and oral veterinary formulations. It has a yellowish colour.

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For more information in our Lipid portfolio please get in touch.

Product name	Chemical description	Physical form	HLB	Monograph**					Routes/applications*				Product description
				FDA IID*	Ph. Eur.	USP/NF	JP/JPE	ChP	Parenteral	Oral	Topical	Auricular/ophthalmic/nasal	

Barrier repair lipids

Cholesterol	Animal derived cholesterol	White crystalline powder		■	■	■					■		Excellent moisturiser with skin conditioning benefits. Very effective in repairing the skin barrier. Powerful W/O emulsifier and emulsion stabiliser. High purity plant derived grade also available.
Crodamol™ ISIS Pharma	Isostearyl isostearate	Colourless liquid	11.0		■						■		Substantive, non-occlusive emollient provides superior moisturisation to the skin. Synergistically improves the skin's natural barrier function, boosting the hydration process, via a unique mechanism. Stabilises the lipid bilayers of the stratum corneum into a more tightly packed structure, thereby improving their effectiveness in preventing water loss. Required HLB value of 11. Recommended topical usage levels of 2-10%.
Pharmalan™	Lanolin	Yellow soft mass		■	■	■					■		Purified grades of anhydrous lanolin is a natural wax that assist in the repair of the skin barrier and aids water absorption. Excellent in topical veterinary applications. Recommended topical usage levels of 1-10%, although can be used neat on skin.

Vaccine adjuvants

Adju-Phos™	Aluminium phosphate gel	Gel											Aluminium phosphate gel specifically developed for use as an adjuvant. Its net negative charge at neutral pH leads to an effective adsorption of positively charged antigens. It boosts the antibody-mediated (Th2) immune response to the antigens, and can be combined with other adjuvants to achieve a well-balanced Th1/Th2 immune response.
Alhydrogel™ 1.3%	Aluminium hydroxide gel 1.8 - 2.2 Al(OH) ₃ , % w/w	Gel			■								Aluminium hydroxide gel with very low conductivity due to the absence of buffering ions. It has a positive charge at a neutral pH and effectively absorbs negatively charged antigens. It boosts the antibody-mediated (Th2) immune response to the antigens, and can be combined with other adjuvants to achieve a well-balanced Th1/Th2 immune response.
Alhydrogel™ 1.5%	Aluminium hydroxide gel 2.1 - 2.5 Al(OH) ₃ , % w/w	Gel	N/A	N/A	■							cGMP Certified Manufacturing site, EU GMP (Part I)	
Alhydrogel™ 2%	Aluminium hydroxide gel 2.7 - 3.3 Al(OH) ₃ , % w/w	Gel			■								
Quil-A™	Saponin	Lyophilised, concentrated, crystal-like powder											A highly purified quillaja saponin product that is very versatile and which can induce a well-balanced immune response to protect against both intracellular (Th1) and extracellular (Th2) pathogens. Developed for veterinary applications.
Squalene	Sugarcane-derived squalene	Clear, essentially colourless liquid			■							cGMP Certified Manufacturing site, EXCI Pact GMP	Pharmaceutical grade squalene obtained by fermentation, with same stability than shark-derived squalene. Squalene is a natural lipid belonging to the terpenoid family. It is an important component in some vaccine formulations. Squalene-based adjuvants increase the immunostimulating effect of a vaccine significantly while keeping a well-established safety profile.
NanoQuil™	Pipeline adjuvant. Only for veterinary applications. NanoQuil is a formulation of cholesterol and Quil-A, resulting in colloidal mixed-micelles. It shows a potent activation of dendritic cells and induction of cytokines along with a strong stimulation of cell mediated (Th1) and antibody-mediated (Th2) immune response and to antigens. It is suitable for vaccines against a wide range of bacterial and viral pathogens. A reduced cell-lytic effect suggests a low reactogenicity helping to optimise a balanced adjuvant dose. The incorporation of saponins in cholesterol can contribute to an increased stability of saponins. NanoQuil is available as an aqueous solution of 15mg/ml as a sample for development purpose only.												

Surfactants and GMP components for veterinary vaccines

Cholesterol	Vegetable derived cholesterol	Powder			■	■	■				■		Cholesterol is an essential ingredient in a wide range of technologies from adjuvants systems, lipid nanoparticles for mRNA delivery to cell culture media. In the last few years, there has been increasing demand for cholesterol from a plant-based source. Our plant-based and parental grade cholesterol provides a high-purity alternative to traditional egg and animal-based cholesterol and is USP/NF, JP and parenteral grade Ph. Eur. compliant.
Span™ 80 HP	Sorbitan oleate	Amber liquid	4.3	■	■	■					■	■	Span HP grades have reduced moisture levels, lower peroxide values and lower acid values. Spans are W/O emulsifiers and when used in combination with ethoxylated sorbitan esters (the Tween range) they contribute to the overall stability of O/W emulsions.
Span™ 83 Pharma	Sorbitan sesquioleate	Amber viscous liquid	3.7	■	■	■						■	Liquid W/O emulsifier and O/W emulsion stabiliser. Used mainly in W/O adjuvant formulations.
Span™ 85 Pharma	Sorbitan trioleate	Amber liquid	1.8	■	■	■					■	■	Span 85 is a liquid W/O emulsifier and O/W emulsion stabiliser used typically in squalene adjuvants systems emulsions.
Super Refined™ Polysorbate 80	Polysorbate 80	Clear, essentially colourless liquid	15.0	■	■	■	■	■	■	■	■	■	Highest purity grade of Polysorbate 80 widely used in parenteral formulation and good stabiliser for proteins.
Super Refined™ Polysorbate 80 POA	Polysorbate 80	Clear, essentially colourless liquid	15.0	■	■	■	■	■	■	■	■	■	Highest purity grade of Polysorbate 80 widely used in parenteral formulation and good solubiliser for liposoluble actives. Pure oleic acid version.
Tween™ 80 HP	Polysorbate 80	Clear yellow liquid	15.0	■	■	■	■	■	■	■	■	■	Promote very stable W/O and O/W emulsion systems when used in association with the Span range. Good solubilisers for liposoluble actives. High Purity (HP) grades can be used to formulate water-in-oil emulsions for vaccine formulations.

Bioprocessing aids

Virodex™ TXR-1	Macrogol lauryl ether 9	Paste/liquid			■	■							Sustainable, REACH-compliant, and cGMP EXCI Pact manufactured.	Virodex™ TXR-1 is a readily biodegradable, nonionic surfactant for viral inactivation and cell lysis, meeting the needs of biopharmaceutical applications as an effective and safe replacement for the traditional detergent, Triton™ X-100. As a next-generation, sustainable detergent, Virodex™ TXR-1, along with its excellent biological compatibility, is recommended to be used in the efficient biomanufacturing of recombinant proteins such as monoclonal antibodies, as well as plasma-derived therapies, viral vector-based therapies and more.
Virodex™ TXR-2	Macrogol 6 glycerol caprylocaprate	Liquid	N/A	N/A	■									Virodex™ TXR-2 is a 40% biobased, nonionic surfactant for viral inactivation and cell lysis, meeting the needs of biopharmaceutical applications as an effective and safe replacement for the traditional detergent, Triton™ X-100. As a next-generation, sustainable detergent, Virodex™ TXR-2, along with its excellent biological compatibility, is recommended to be used in the efficient biomanufacturing of recombinant proteins such as monoclonal antibodies, as well as plasma-derived therapies, viral vector-based therapies and more.

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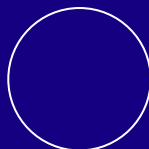
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