



SheffCoat™
Aqueous based
coating systems

Customised immediate release
and enteric film coating systems



A name you know you can trust

For more than 75 years, we have earned our reputation for reliability and excellence in serving the biotech, pharmaceutical and nutrition markets by delivering unsurpassed product value, enhanced opportunities for supply chain consolidation, and new technology innovation. We bring together our superior products with new innovative solutions and market-driving alternatives to help our customer succeed in today's challenging global marketplace.



As part of the Kerry Group, a \$7 Billion leader, we can provide you the global technical service, regulatory and application support whether this is in the development process, or troubleshooting commercial production challenges.

We make it our business to exceed our customers' expectations every day. We collaborate directly with formulators in the development of new drugs and delivery systems. We understand the requirements and regulations needed to succeed.

SheffCoat™

Benefits

1. Pre-blended, ready-to-use dry clear or coloured coatings that optimize performance and efficiency
2. Complete line of cost effective aqueous coating systems
3. Based on industry standard polymers, pigments, and plasticizers that meet all regulatory requirements
4. Applied with standard film coating processes and equipment
5. R&D application labs for custom & collaborative formulation development
6. Match or exceed performance of current coating system
7. Precise colour matching of existing coating system and assurance of batch to batch colour consistency

A name you know you can trust

The standard of comparison

Building on 75 years of innovation, commitment and reliability as a world class excipient supplier, Kerry has created a one step, ready-to-use system to match your existing coating and colour, while offering a full spectrum of best-in-class, cost effective solutions for new product development.

SheffCoat™ film coating systems are based on industry standard, regulatory accepted polymers, pigments and plasticizers that are applied with standard film coating processes and equipment. With our extensive knowledge and experience we can match or exceed the functionality of any competitive coating system as well as custom match or create any desired colour. We provide formulation, technical, regulatory and quality support through every step of your development, scale-up and production process.

Manufacturing expertise

SheffCoat™ coating systems are manufactured in Norwich, NY which is a ISO 14001 certified establishment which utilizes CFR 21 sections 210 and 21 as well as in Vadodara, India and Barueri, Brazil. We are committed to exceeding the cGMP expectations of our pharmaceutical customer base with our extensive quality assurance programs.

Each batch is produced in accordance within approved specifications and are GMP/GLP compliant with IPEC guidelines as well as regional requirements globally.

Our individual and isolated manufacturing suites have separate air handling systems. We have various blenders allowing for accurate scale-up and enabling batch sizes up to 1,250kg.

Global technical support

Our core technical expertise and extensive knowledge in industrial pharmaceutical tablet coating enables us to support our customers in optimizing SheffCoat™ performance and efficiency. We are available to assist customers with on-site coating trials and problem solve with production issues.

Regulatory and quality assurance

Kerry has a dedicated regulatory group to ensure product compliance to global regulatory requirements. Our regulatory team provides full customer support to customers in every step of the process including regional regulatory agency compliance, vendor forms, and audits to complete formulation changes.

Changing to SheffCoat™ assures seamless changes from your current formulations' quality and performance while improving your cost competitiveness, and flexibility.



Individual and Isolated suites have separate air handling systems.



Various blenders with liquid addition and high shear mixing.



Accurate scale-up and multiple batch sizes.

New product formulation

A grid of white pill containers filled with yellow and teal tablets. The containers are arranged in a 3x2 grid, with the top row partially cut off. The yellow tablets are in the left column, and the teal tablets are in the right column. The background is a light, neutral color.

When you need something unique, Kerry has the technical and applications expertise and is ready to work with your R&D team to create a unique solution.

Our state of the art pilot plants and application labs in the US, Brazil, Turkey, and India are fully equipped to perform tablet functionality testing to ensure our products conform to the highest standards. Our application experts will collaborate with you to develop a customised formulation that will optimize performance and efficiency while using ingredients that meet all regulatory and consumer requirements.

Kerry's application technicians can provide solutions to solve coating issues such as:

- > Soft or friable cores
- > Uneven or inconsistent cores
- > Heat sensitive APIs
- > Moisture sensitive APIs
- > Process efficiency requirements
- > Formulations with coprocessed excipient

Custom colours and support



Colour match sources can include, but are not limited to

- > Existing formulations
- > Previously coated tablets
- > Pantone number
- > PDR or on-line references

R&D/Application support

- > Custom collaborative coating development capabilities
- > Colour matching of existing coating system
- > Pilot scale coating trials
- > Extensive knowledge in scale-up into manufacturing
- > Complete tablet functionality testing capabilities
- > Capabilities to match or exceed performance of current coating systems

SheffCoat™

Standard colour collection

Coloured tablet coatings provide brand recognition and dose discrimination functions, as well as mask the tablet core. Kerry has coatings to meet label requirements, regulatory requirements and stability needs for all regions. We offer a portfolio of off-the-shelf colours that can also be customised to create a distinctive colour.

Need to precisely match an existing colour? We understand the importance and we get it right. Visual and spectrophotometric colour match specifications are part of every product.

Contact us for customised colours per your requirements.

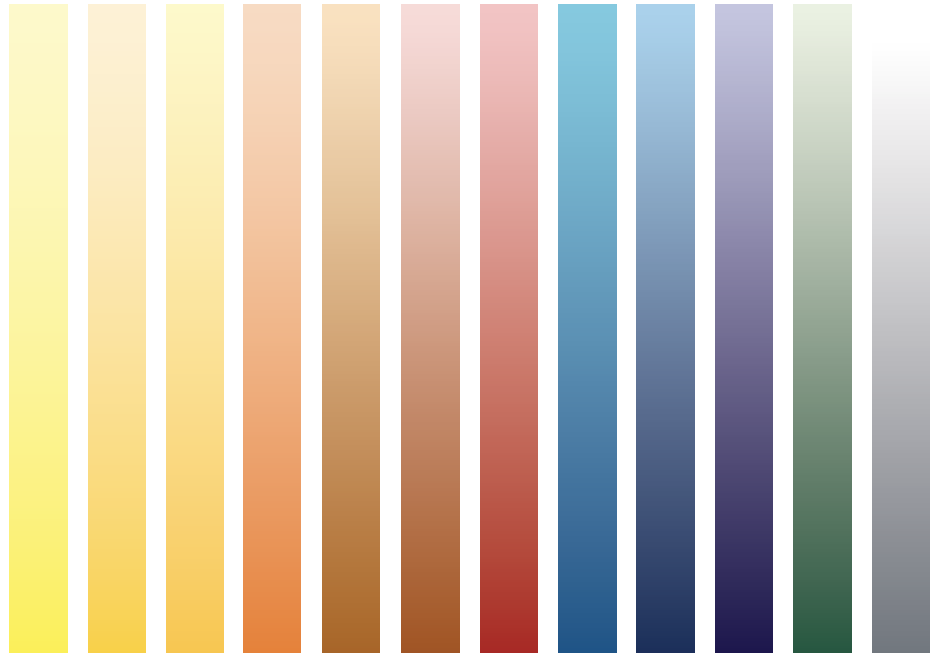


PACKAGING AND SAMPLES

All samples are shipped with a sufficient quantity of coating powder formulations so you can evaluate the colour prior to performing any coating trials. Coated placebos can be shipped with the sample upon customer request.

SheffCoat™ is packaged in a 25kg poly lined, tamper evident boxes. Customised packaging and batch sizes available upon request.

Sample sizes available are 0.5kg, 1kg or 5kg.



SheffCoat™ immediate release offerings

Coatings overview

SheffCoat™ Immediate Release film coatings allows the customer to select from numerous plasticizers and a wide range of colourants to customize a film coating that is compatible with your API and regional regulatory requirements. We offer a variety of different viscosities and film strengths to exactly match your existing film coating or customize a film coating that will provide superior film performance and adhesion while providing excellent logo definition without compromising disintegration time or other important tablet properties.

HPMC based film coatings		
SheffCoat™ L with lactose	SheffCoat™ CG Global acceptance	SheffCoat™ Original
SheffCoat™ Enhance with flavour	SheffCoat™ MP with PVA	
SheffCoat™ HS with HPC	SheffCoat™ EC with ethylcellulose	

SheffCoat™ immediate release offerings

PVA based film coatings

SheffCoat™ PVA

SheffCoat™ PVA+
with lecithin

Clean label coatings

SheffCoat™ NP
Natural pigment

SheffCoat™ TF
Titanium free

Enteric coatings

SheffCoat™ ENT MA
Acrylate copolymer

***SheffCoat™ ENT HPMC-P**
HPMC phthalate

* only available in LATAM and APMEA



SheffCoat™ | Optimization matrix

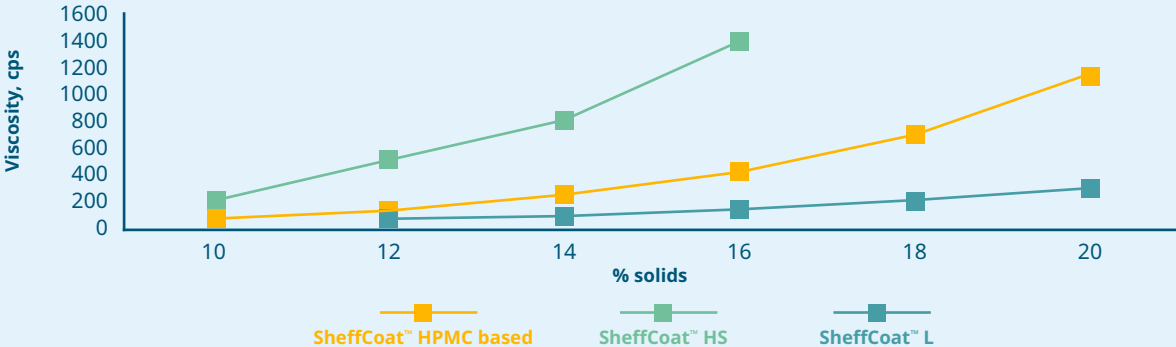
	SheffCoat™	SheffCoat™ CG	SheffCoat™ PVA	SheffCoat™ PVA+	SheffCoat™ HS	SheffCoat™ L
Polymer & other key ingredients	HPMC	HPMC+ glycerol	PVA	PVA+ Lecithin	HPMC+ HPC	HPMC+ Lactose
Moisture sensitive API - aqueous coating			✓	✓	✓	
Moisture sensitive API - alcohol or solvent coating						
API sensitive to plasticizer interaction					✓	
Waxy or poor adhesion cores					✓	✓
Soft tablets (herbal formulations)			✓		✓	
Low viscosity/ high solids solution			✓			
Improved logo definition	✓	✓	✓			✓
Cleaner label	✓	✓				
Prop 65 restrictions	✓	✓			✓	
Titanium dioxide free	✓	✓	✓			
Natural pigments	✓	✓	✓			
Taste or odor masking			✓			
Glossy finish	✓	✓				
Gloss topcoat	✓	✓	✓			
Precoat for friable cores					✓	
Precoat for enteric coating	✓	✓				
Superior slip properties to finished tablet						
Taste enhancement						
Aqueous enteric coating						
Alcohol or solvent based coating						
Global acceptance		✓				

SheffCoat™ | Optimization matrix

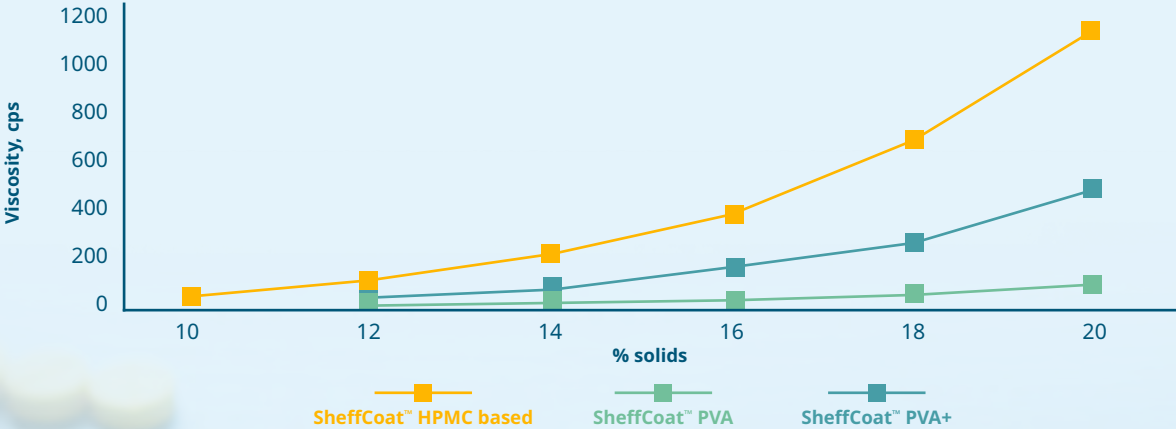
	SheffCoat™ Enhance	SheffCoat™ MP	SheffCoat™ NP	SheffCoat™ TF	SheffCoat™ ENT MA	SheffCoat™ ENT HPMC-P	SheffCoat™ EC
Polymer & other key ingredients	HPMC+ flavour	HPMC+ PVA	HPMC+ natural pigments	HPMC or PVA	Acrylate copolymer	HPMC phthalate	HPMC+ ethylcellulose
Moisture sensitive API - aqueous coating							
Moisture sensitive API - alcohol or solvent coating							✓
API sensitive to plasticizer interaction							
Waxy or poor adhesion cores		✓					
Soft tablets (herbal formulations)							
Low viscosity/ high solids solution							
Improved logo definition		✓					
Cleaner label			✓	✓			
Prop 65 restrictions		✓					
Titanium dioxide free				✓			
Natural pigments		✓	✓				
Taste or odor masking	✓						✓
Glossy finish							
Gloss topcoat							
Precoat for friable cores							
Precoat for enteric coating							
Superior slip properties to finished tablet							
Taste enhancement	✓						
Aqueous enteric coating					✓	✓	
Alcohol or solvent based coating							✓
Global acceptance							

SheffCoat™ viscosities

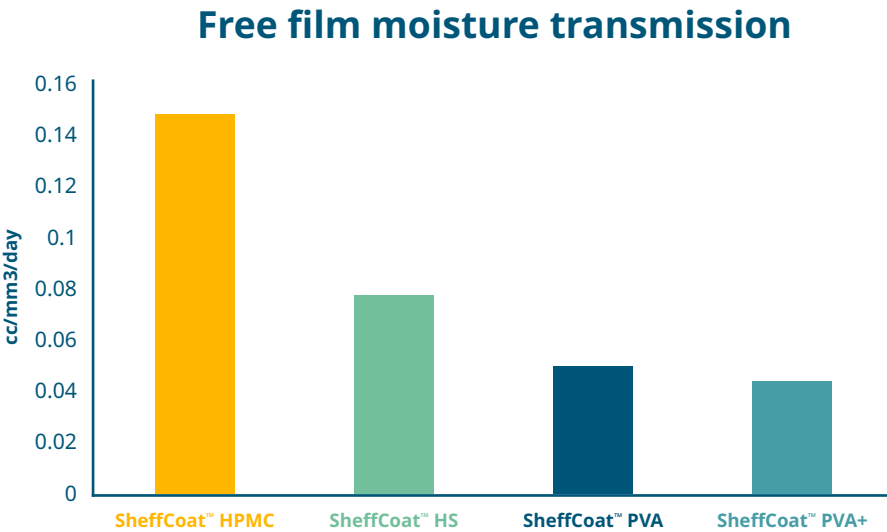
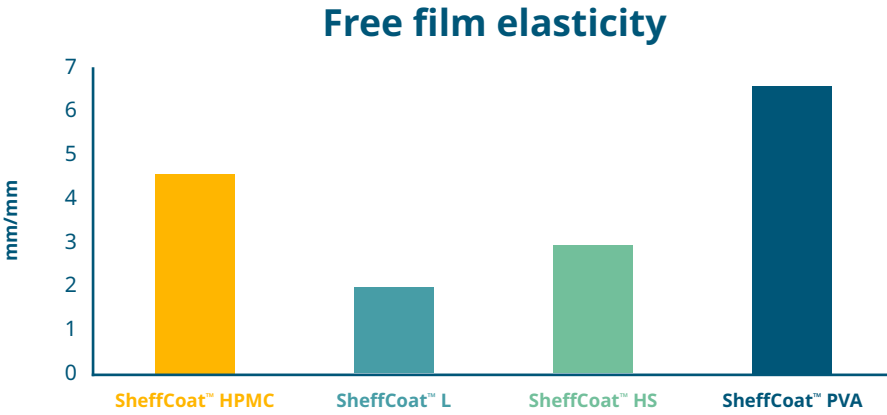
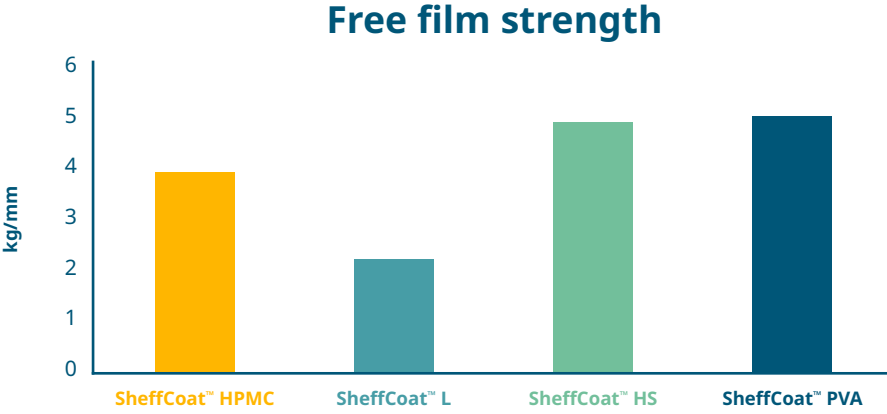
SheffCoat™ viscosities – cellulose based



SheffCoat™ viscosities – PVA based



SheffCoat™ film strength, elasticity and moisture transmission



Placebo's were coated to 3% weight gain. PEG was used as the plasticizer.

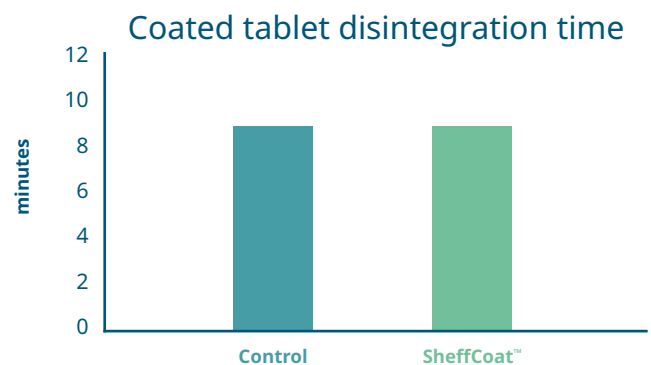
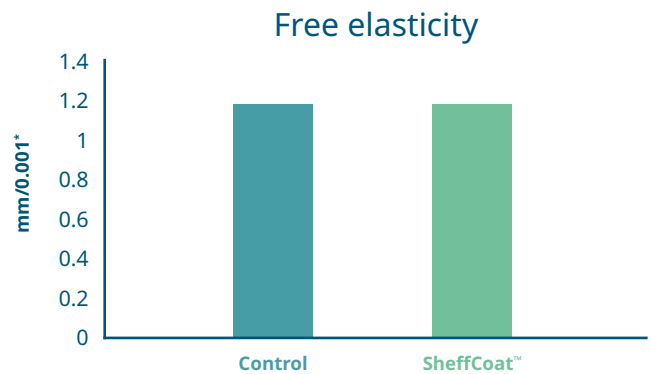
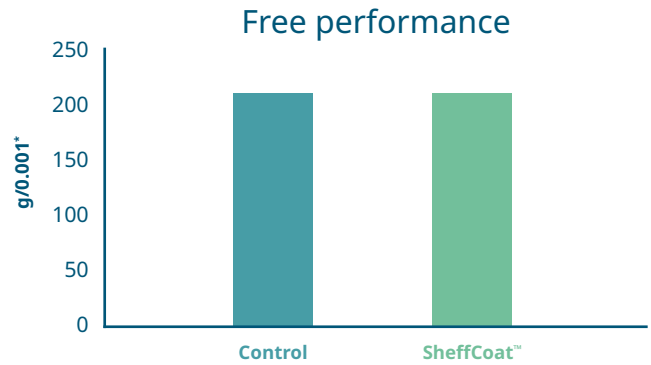
The original SheffCoat™

SheffCoat™ HPMC base

- > The most basic film coating; widely used across the pharmaceutical industry for decades
- > Numerous plasticizers available; plasticizers chosen to be compatible with API and regional regulatory requirements, or label requirements
- > Wide range of colours available; chosen to be compatible with API and regional regulatory requirements, or customers preferences
- > Different viscosities and molecular weights available
- > SheffCoat™ is equivalent in performance and appearance to other HPMC coatings on the market

Film performance

SheffCoat™ film coating system provide exact matches to competitive products with comparable formula and functionality without compromising important film attributes.



SheffCoat™ PVA

SheffCoat™ PVA (PVA base)

- > Applied with 20% solids spray suspensions for improved efficiency over HPMC
- > Superior film coating to HPMC
- > Ideal “slip” for bottle packaging equipment and blister pack machines
- > No change in tablet dissolution and compared to HPMC
- > Excellent adhesion properties

SheffCoat™ PVA+ (PVA + lecithin)

SheffCoat™ PVA+ provides the same benefits of a traditional PVA coating but contains lecithin for additional moisture protection.

SheffCoat™ PVA
(PVA base)

SheffCoat™ PVA+
PVA + Lecithin



SheffCoat™ HS | SheffCoat™ L

SheffCoat™ HS

HPMC based coating platform with increased film elasticity and adhesion

Some tablets have softer cores and may need a very durable coating with increased adhesion in order to ensure the tablet core does not erode during the coating process. There are also certain APIs that are extremely sensitive to moisture. The addition of HPC provides improved film characteristics to overcome these issues.

- > HPC adds film elasticity and adhesion
- > HPC may also increase viscosity at higher usage rates, slightly lowering solids content of spray suspension

SheffCoat™ L

HPMC based coating platform with improved processing efficiency and less cost

The need for higher than 15% solids spray suspension is desired when faster processing times are needed because the tablets cannot have prolonged exposure to heat and moisture. The addition of a carbohydrate provides the increased processing efficiency without using PVA.

- > Creates adequate film and is low cost alternative to HPMC
- > Excellent logo definition

SheffCoat™ HPMC base

SheffCoat™ HS (High Strength)
HPMC + HPC

SheffCoat™ HPMC base

SheffCoat™ L
HPMC + Lactose

SheffCoat™ Enhance

SheffCoat™ Enhance

HPMC based coating platform with improved taste and aroma

SheffCoat™ Enhance is an HPMC based coating system designed to incorporate flavors in to the coating which affect aroma and taste, while maintaining a uniform, homogeneous, and robust film coating on the tablet.

- > Improves taste and aroma
- > Robust film coating
- > Enhance consumers perception and experience of tablet

SheffCoat™ HPMC base

SheffCoat™ Enhance
HPMC + Flavor



SheffCoat™ MP

SheffCoat™ MP

HPMC based coating platform with improved processing efficiency and film

It is possible to increase processing efficiency of a basic HPMC formulation while maintaining film strength and adhesion. Instead of replacing HPMC with a carbohydrate, a high performing film forming polymer such as PVA is used in combination. Provides the benefits of HPMC while providing higher solid and better elasticity

- > Ability to coat at lower temperatures than PVA
- > PVA allows for higher solids in spray suspension – faster processing times
- > PVA provides increased elasticity over HPMC

SheffCoat™ HPMC base

SheffCoat™ MP (Mixed Polymer)
HPMC + PVA

SheffCoat™ CG

SheffCoat™ CG

**Clear HPMC based coating system
with global regulatory acceptance**

Sheffcoat™ CG is an HPMC based coating system designed for regulatory acceptance in most major pharmaceutical and dietary supplement markets.

It is a strong, clear coating with good adhesion, and elasticity that provides formulators with ease when selecting a globally acceptable film coating.

- > Regulatory acceptance in most major markets
- > California Prop 65 compliant
- > Non-GMO (validated)
- > Kosher and Halal certified
- > Composed entirely of plant based ingredients
- > Strong, clear coating with good adhesion and elasticity

SheffCoat™ HPMC base

**SheffCoat™ CG (Clear Global)
HPMC + Glycerol**

SheffCoat™ NP

SheffCoat™ NP

Natural pigment coating

Sheffcoat™ NP uses all natural pigments and are specifically formulated to allow for the cleanest label and best possible light stability, while maintaining important film coating properties, such as high solid to viscosity ratio, quick dispersion, and strong, durable films on the tablet surface.

- > Allows for cleaner label claims
- > Colours free from artificial pigments
- > Regulatory acceptance in most markets

SheffCoat™ HPMC base

SheffCoat™ NP
HPMC formulated
with all natural pigments

SheffCoat™ TF

SheffCoat™ TF

Titanium dioxide free

SheffCoat™ TF meets consumer demands for cleaner label while providing ease of regulatory compliance for use in dietary & nutritional supplements as well pharmaceutical products by removing Titanium Dioxide.

- > Allows for clean label claim and regulatory compliance
- > Provides aesthetics normally associated with TiO2
- > Minimal changes to typical process conditions and film coat weights
- > Customisable to meet colour requirements

SheffCoat™ base

SheffCoat™ TF
Various polymer options available

SheffCoat™ enteric film coatings

SheffCoat™ enteric film coatings

SheffCoat™ ENT is a functional delayed release or enteric film coating that releases the API at a specific pH and/or area of the digestive tract.

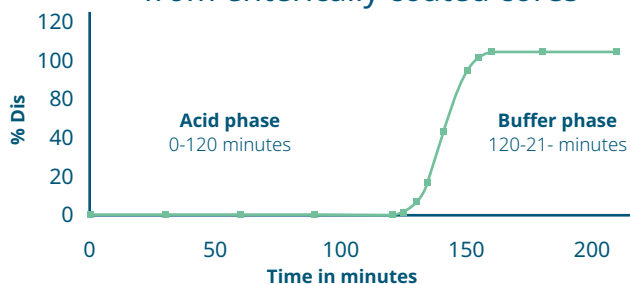
- > Complete ready-to-spray powder formulations
- > Consistent and reproducible delayed release performance
- > Targeted drug delivery for applications including tablets, granules, and beads
- > pH Dependent Release
- > Solubilizes at pH 5.5
- > Variety of plasticizers available

Enteric coatings

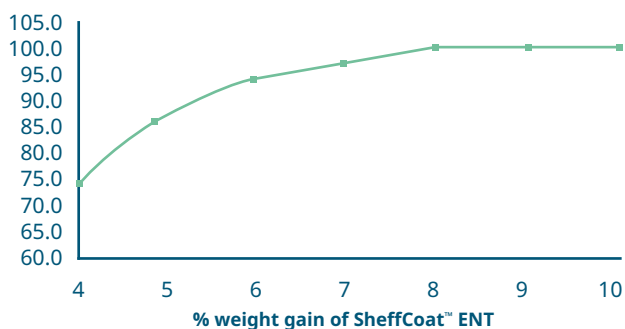
SheffCoat™ ENT MA
Acrylate copolymer

SheffCoat™ ENT HPMC-P
HPMC phthalate

Release of ASA
from enterically coated cores



% Tablets passing
modified USP test





KERRY

SheffCoat™
kerry.com/pharma

