

KERRY

Leading to Better

SheffCoat™

Aqueous Based Coating Systems

Customized Immediate Release
& Enteric Film Coating Systems

kerry
.com

A Name You Know 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 \$6 Billion leader, we can provide you the global technical service, regulatory and application support whether this is in the development process, or trouble-shooting 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

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

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 color, 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 color. 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 and in Vadodara, India. 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 with

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 1,250 kg.

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.

**Drug Master Files are available.*



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

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 customized 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/API



Color 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
- Color 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 system

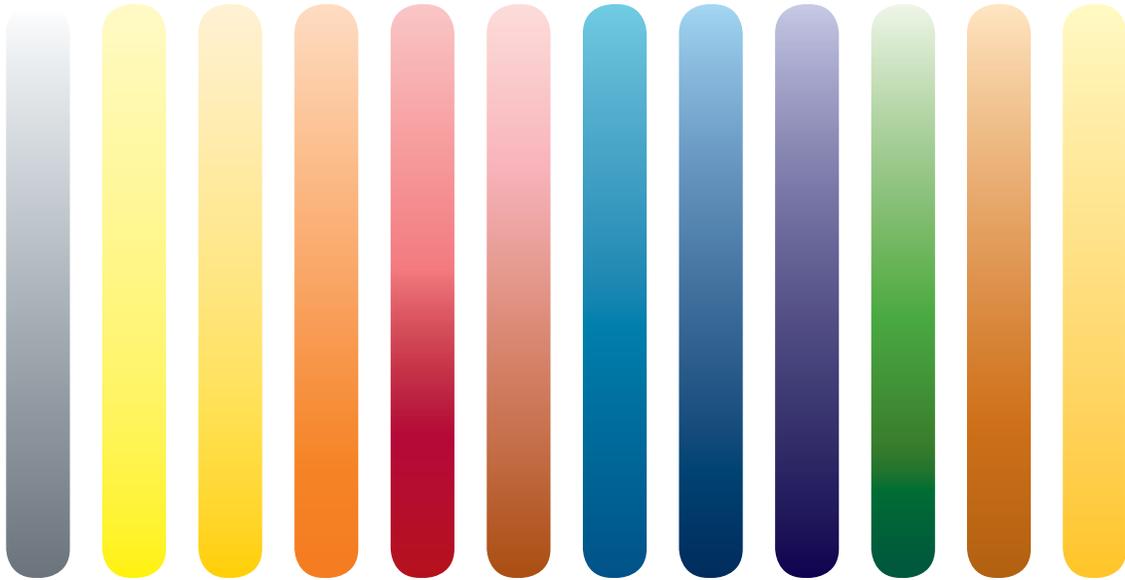
SheffCoat™

Standard Color Collection

Colored 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 colors that can also be customized to create a distinctive color.

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

[Contact us for customized colors per your requirements.](#)



Packaging and Samples

All of our samples are shipped with coated placebos and a sufficient quantity of coating powder formulations so you can evaluate the color prior to performing any coating trials.

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

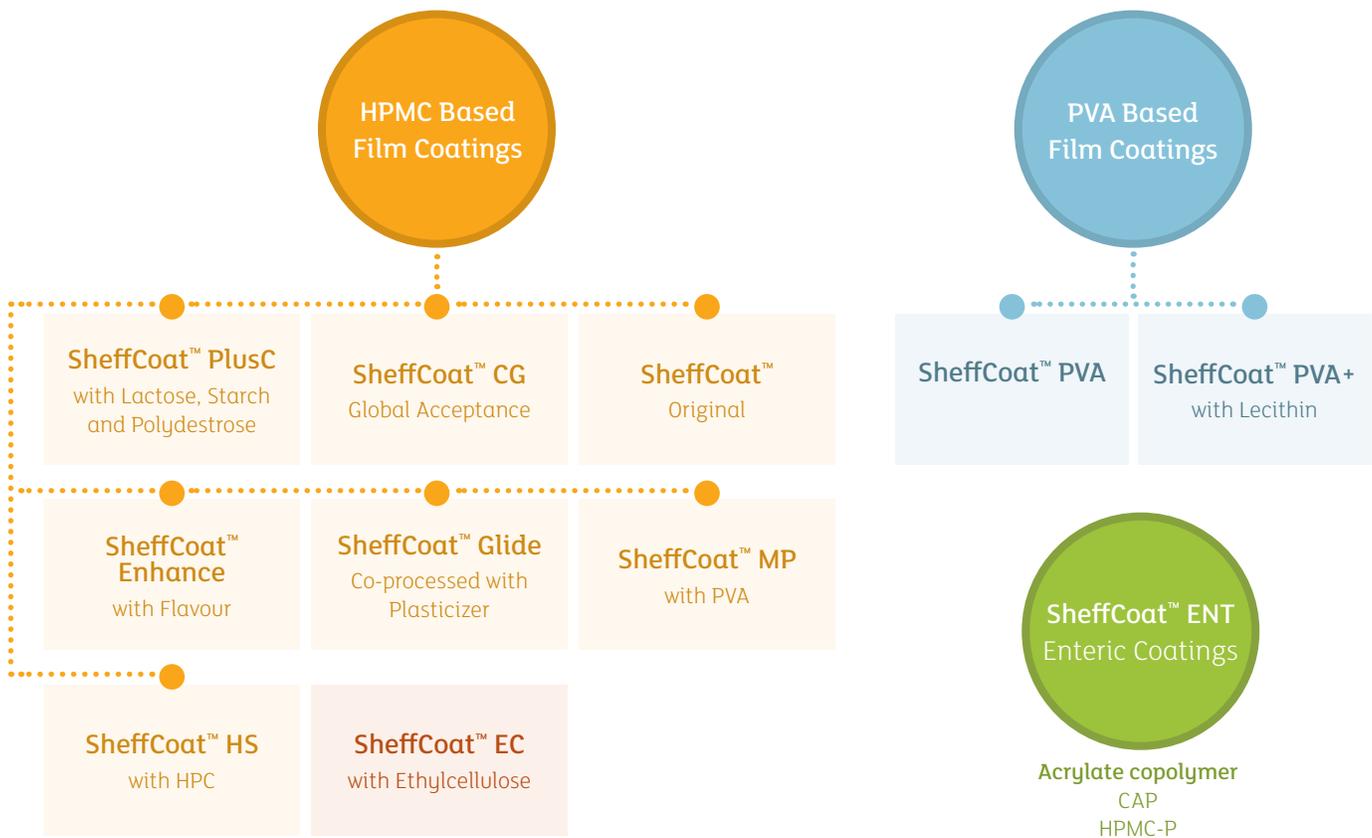
Standard sample is 0.5 kg and larger samples are available upon request.

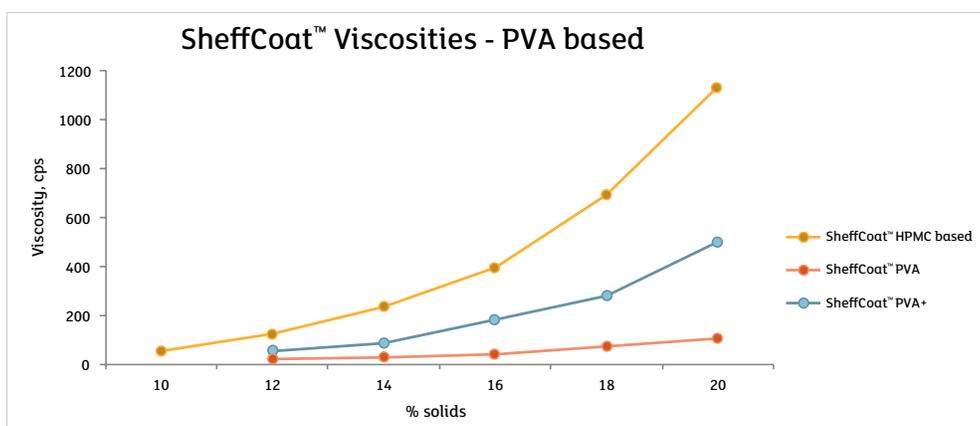
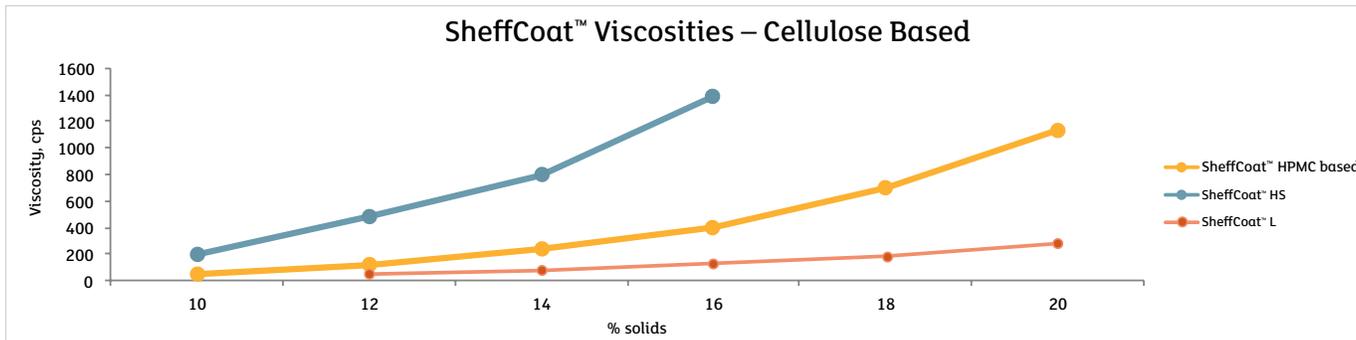


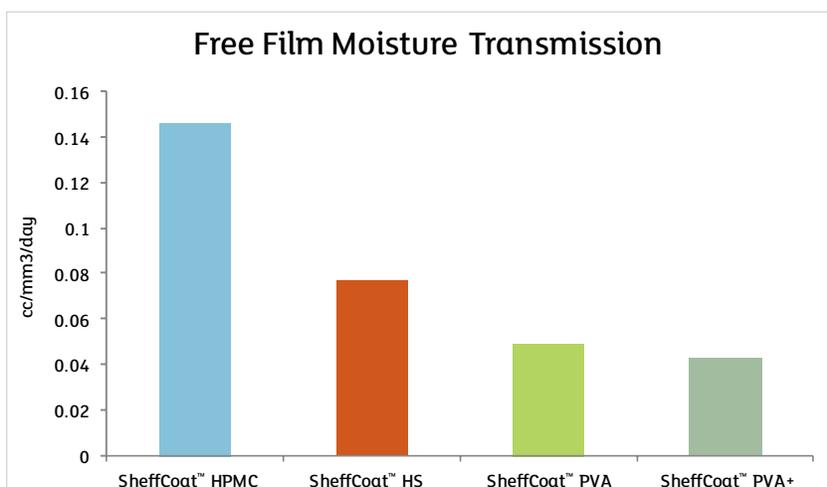
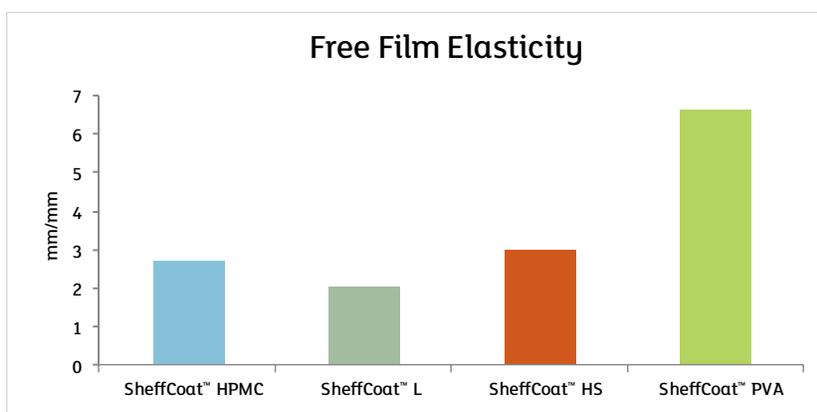
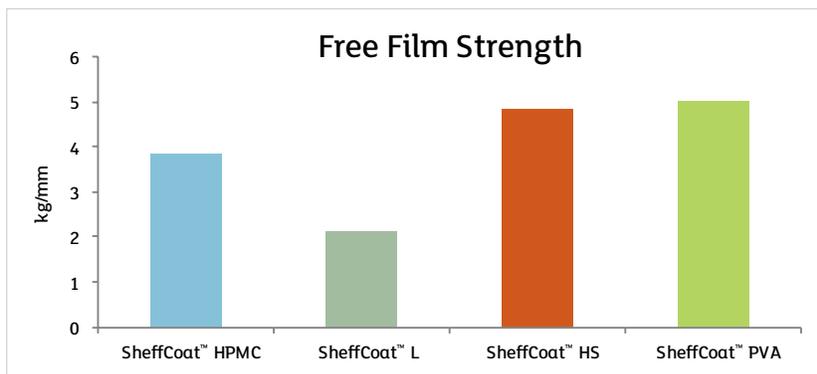
SheffCoat™ Immediate Release Offerings

Coatings Overview

SheffCoat™ Immediate Release film coatings allows the customer to select from numerous plasticizers and a wide range of colorants 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.







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



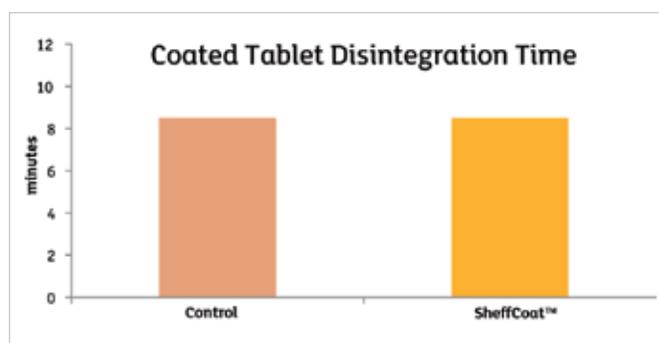
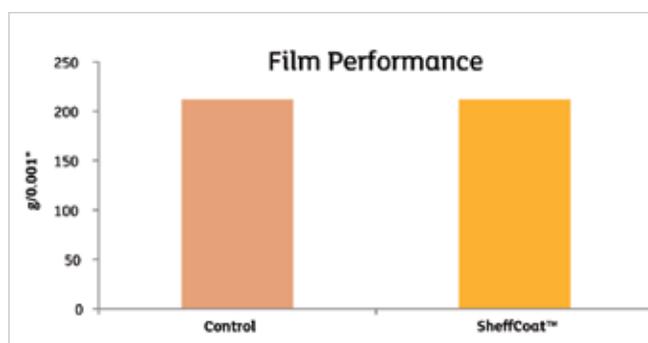
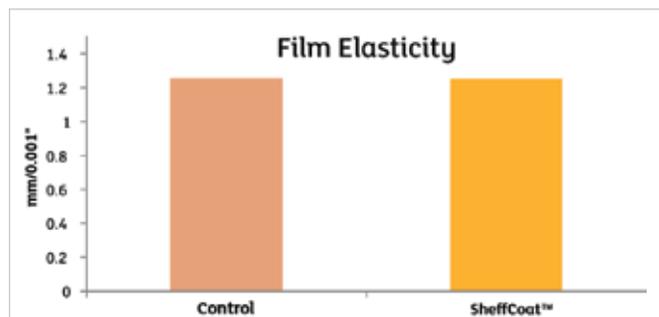
The Original SheffCoat™

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 colors 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

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

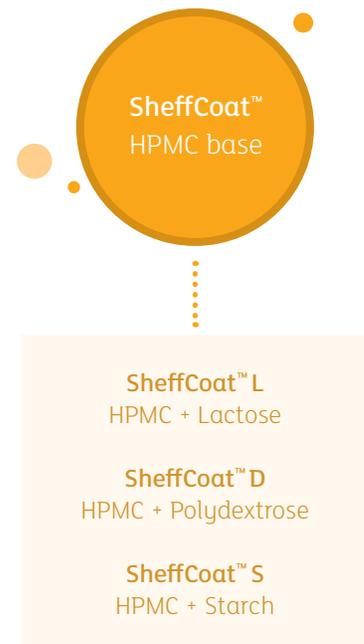


SheffCoat™ PlusC Systems

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™ Glide

Coprocessed HPMC/plasticizer formulation providing superior slip to finished tablet

Sheffcoat Glide™ is an HPMC based coating system designed to help with ease of swallow of large or irregular shaped tablets. It is specially formulated by combining the plasticizer with the polymer in a proprietary way that dramatically improves the slip of the coating. The result is a one-step coating, that has excellent film forming properties, that provides superior slip to the finished tablet.

- Superior slip properties to finished tablet
- Improves the ease of swallowing large or irregular shaped tablets
- Excellent film forming properties



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™ 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™ 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™ 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

SheffCoat™ ENT
Acrylate Copolymer

CAP

HPMC-P

Film Performance

