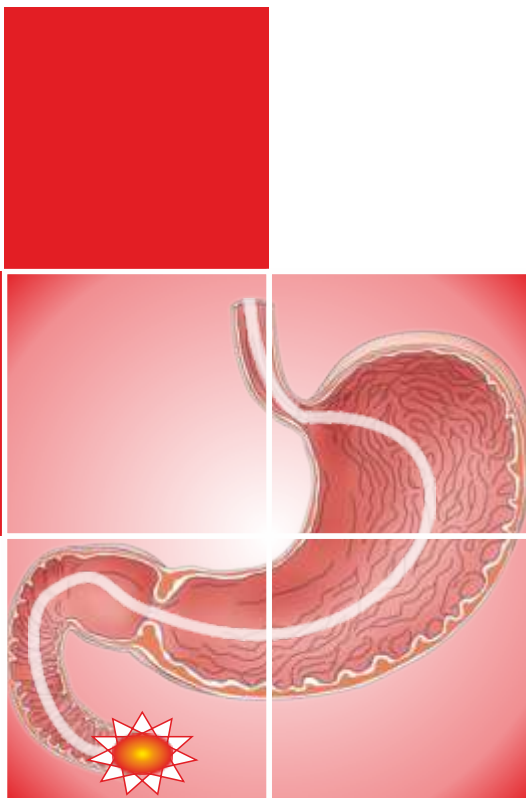




# DRUGCOAT<sup>®</sup>

[www.vikramthermo.com](http://www.vikramthermo.com)



*Excellence in Pharma Polymer*



## *Something about us.....*



Vikram Thermo (India) Limited, was established in the year 1984, near Ahmedabad, Gujarat for manufacturing Di-Phenyl Oxide in the name of Vikram Enterprise Private Limited, a pioneer in the manufacturing of DPO. Later on company also entered into the business of developing pharma polymer products – Acrylic polymers for various applications in pharmaceutical coating. Over the years company has developed full range of polymers in Methacrylic acid family for different applications such as enteric, delayed release, sustained release, taste masking etc. under the brand name **DRUGCOAT**.

Most of these coating polymers were developed through constant research & development work in company's R&D centre and today company claims it's products to be of world class quality conforming to highest standard technical specifications as prescribed in various monographs. Company has a state-of-the-art manufacturing facility certified with International EXCiPACT GMP certificate. 'VTIL' today is proud of it's full range of products and claimed to be the largest producer in this class of pharma polymers in India. It has acquired a clear leadership position in the industry.

# DRUGCOAT<sup>®</sup>

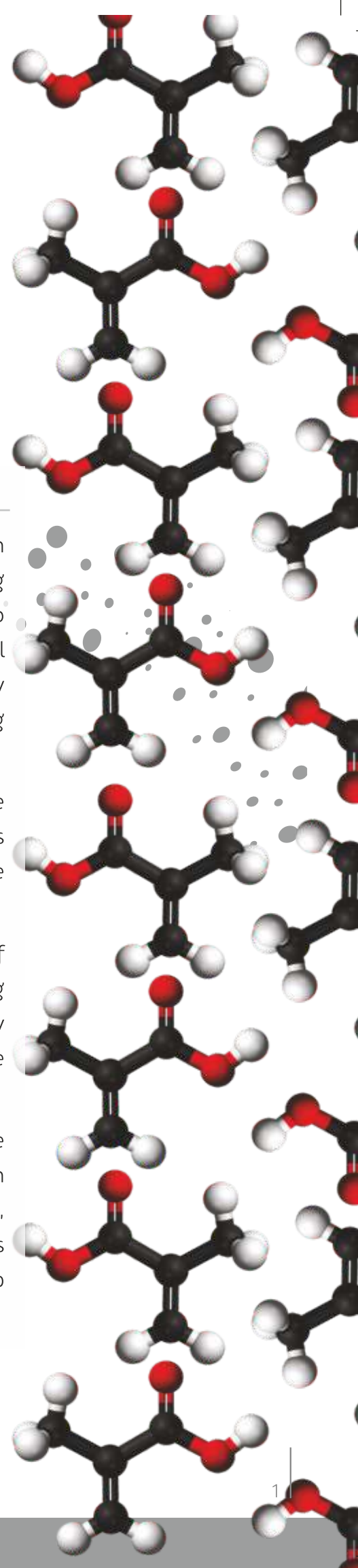
## DRUGCOAT

Coating in oral solid dosage form is now very commonly used in pharmaceutical industry. However, coating as such has its beginning with bitter taste masking of medicines in good old days with the help of sugar coating. This was very popular in Nutraceuticals & Herbal medicines. Later on film coating concept came first time in early 1950's courtesy Dr. Wurster under who's name air suspension coating was patented.

Over the years, there have been several improvements in both the coating technologies as well as the coating material, which has brought the concept of **functional coating** as an important field in the pharmaceutical industry.

Ultimately, convenience, efficacy, safe drug delivery and economy of entire coating system are the four major criteria that were the guiding factors in evolving ideal drug delivery system or a **Novel Drug Delivery System** i.e. **NDDS**. This is possible only with the help of suitable choice of Acrylate polymers.

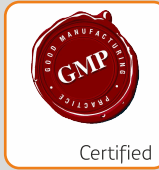
Thus it is obvious that our **DRUGCOAT** polymer range of products have excellent potential as versatile & unique in different application in NDDS including customized and newer application. Therefore, pharma industry has now started looking for newer coating materials and is in a process of shifting from conventional coating materials to **NEXTGEN** polymer i.e. Methacrylic acid copolymers





# PRODUCT RANGE

DRUGCOAT SERIES	MONOGRAPHS	PHYSICAL FORM
<b>ENTERIC FORMULATION</b>		
<b>AQUEOUS BASE</b>		
DRUGCOAT L 30D	USP/NF: Methacrylic Acid And Ethyl Acrylate Copolymer Dispersion Ph. Eur.: Methacrylic Acid-Ethyl Acrylate Copolymer(1:1) Dispersion 30%	Aqueous Dispersion 30%
DRUGCOAT L 100-55	USP/NF: Methacrylic Acid And Ethyl Acrylate Copolymer Ph. Eur.: Methacrylic Acid- Ethyl Acrylate Copolymer (1:1) Type A	Powder
DRUGCOAT L 100-55D	USP/NF: Partially-Neutralized Methacrylic Acid & Ethyl Acrylate Copolymer Ph. Eur.: Methacrylic Acid- Ethyl Acrylate Copolymer (1:1) Type B	Powder
DRUGCOAT FS 30D		Aqueous Dispersion 30%
<b>NON AQUEOUS BASE</b>		
DRUGCOAT L 100	USP/NF: Methacrylic Acid And Methyl Methacrylate Copolymer (1:1)	Powder
DRUGCOAT L 12.5	Ph. Eur.: Methacrylic Acid – Methyl Methacrylate Copolymer (1:1)	Organic Solution 12.5%
DRUGCOAT S 100	USP/NF: Methacrylic Acid And Methyl Methacrylate Copolymer (1:2)	Powder
DRUGCOAT S 12.5	Ph. Eur.: Methacrylic Acid – Methyl Methacrylate Copolymer (1:2)	Organic Solution 12.5%
<b>TASTE MASKING &amp; PROTECTIVE FORMULATION</b>		
DRUGCOAT E 100	USP/NF: Amino Methacrylate Copolymer Ph. Eur.: Basic Butylated Methacrylate Copolymer	Granules
DRUGCOAT E PO		Powder
DRUGCOAT E 12.5		Organic Solution 12.5%
<b>SUSTAINED RELEASE FORMULATION</b>		
DRUGCOAT RL 100	USP/NF: Ammonio Methacrylate Copolymer, Type A Ph. Eur.: Ammonio Methacrylate Copolymer, Type A	Granules
DRUGCOAT RL PO		Powder
DRUGCOAT RL 12.5		Organic Solution 12.5%
DRUGCOAT RS 100	USP/NF: Ammonio Methacrylate Copolymer, Type B Ph. Eur.: Ammonio Methacrylate Copolymer, Type B	Granules
DRUGCOAT RS PO		Powder
DRUGCOAT RS 12.5		Organic Solution 12.5%
DRUGCOAT NE 30D	USP/NF: Ethyl Acrylate And Methyl Methacrylate Copolymer Dispersion Ph. Eur.: Polyacrylate Dispersion 30%	Aqueous Dispersion 30%



## DISSOLUTION PROPERTIES

Dissolve above pH 5.5

Dissolve above pH 7.0

Dissolve above pH 6.0

Dissolve above pH 7.0

Dissolve up to pH 5.0

pH-independent swelling

### Enteric Formulations

**Duodenum pH > 5.5**  
 DRUGCOAT L 30 D  
 DRUGCOAT L 100-55  
 DRUGCOAT L 100-55D

**Jejunum pH 6-7**  
 DRUGCOAT L 100  
 DRUGCOAT L 12.5

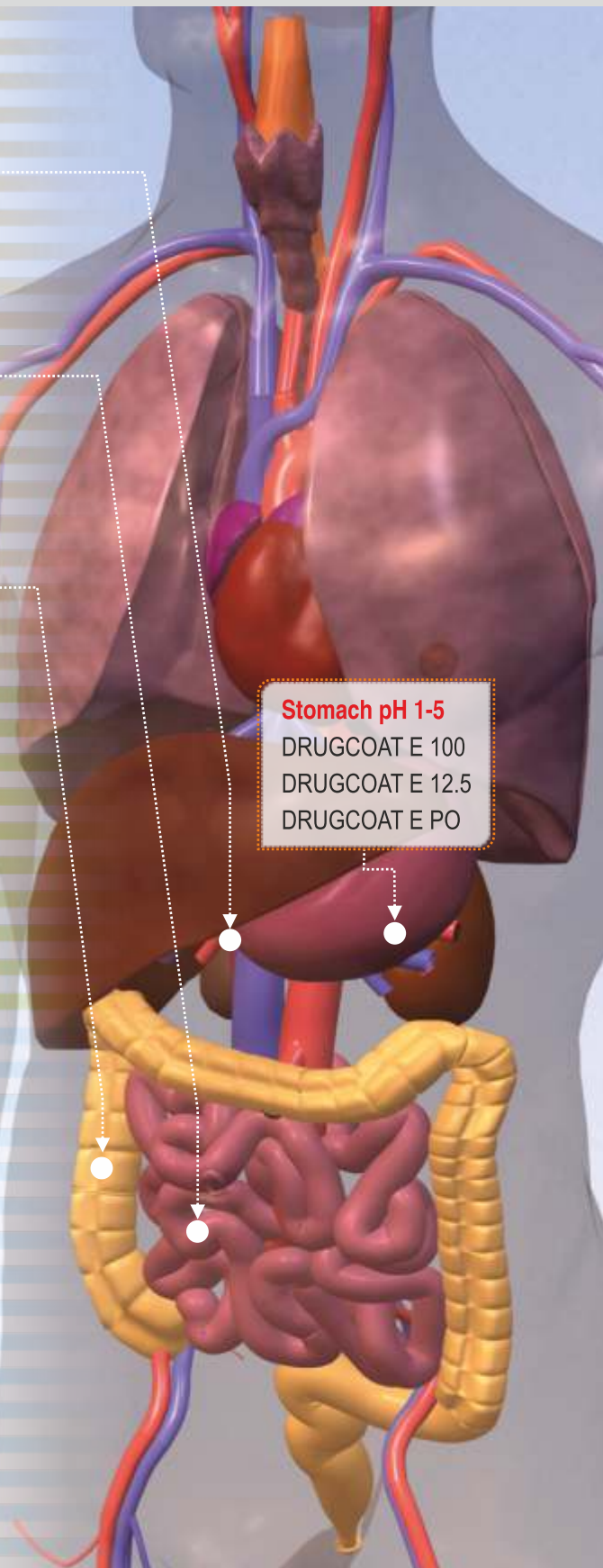
**Colon pH > 7**  
 DRUGCOAT S 100  
 DRUGCOAT S 12.5  
 DRUGCOAT FS 30D

### Protective Formulations

**Stomach pH 1-5**  
 DRUGCOAT E 100  
 DRUGCOAT E 12.5  
 DRUGCOAT E PO

### Sustained-Release Formulations

**Time controlled release  
 pH independent**  
 DRUGCOAT RL PO  
 DRUGCOAT RL 100  
 DRUGCOAT RL 12.5  
 DRUGCOAT RS PO  
 DRUGCOAT RS 100  
 DRUGCOAT RS 12.5  
 DRUGCOAT NE 30D



## ENTERIC FORMULATION:

Many API undergo degradation in hostile acidic environment of stomach. Many API irritate the gentle gastric mucosa. This irritation in severe cases can lead to permanent damage to gastric mucosa causing peptic ulcer.

In either case, it is essential to prevent the release of API in stomach and this can be achieved by **DRUGCOAT** L and S series polymers.

These polymers can additionally be used to deliver API to a specific site in the GI tract. This results in site specific targeted drug delivery.

DRUGCOAT SERIES	PHYSICAL FORM	DISSOLUTION PROPERTIES	US-DMF	FUNCTIONALITY	
<b>AQUEOUS BASE</b>					
DRUGCOAT L30D	Aqueous Dispersion 30%	Dissolve above pH 5.5	Available	Anionic polymers with methacrylic acid as a functional group	
DRUGCOAT L 100-55	Powder				
DRUGCOAT L 100-55D	Powder	Dissolve above pH 7.0			
DRUGCOAT FS 30D	Aqueous Dispersion 30%				
<b>NON - AQUEOUS BASE</b>					
DRUGCOAT L 100	Powder	Dissolve above pH 6.0	Available		
DRUGCOAT L 12.5	Organic Solution 12.5%				
DRUGCOAT S 100	Powder	Dissolve above pH 7.0			
DRUGCOAT S 12.5	Organic Solution 12.5%				

## Why DRUGCOAT L and S series?

- For pH-dependent drug release
- For Protection of API from gastric fluid
- For Protection of gastric mucosa from API
- For GI and colon targeting
- To insulate hygroscopic cores
- To Increase storage stability
- Better stability compared to phthalate group coating agent
- For Enteric coating of API formulation like Diclofenac Sodium, Ketoprofen, Indomethacin, Omeprazole, Pantoprazole, Rebeprazole, Bisacodyl, Aspirin, Sodium valporate

## ADDITIVES:

### Plasticizer

It is recommended to add 10-20% plasticizer on dry polymer substance into the DRUGCOAT L and S Series Solution or Dispersion, to obtain films adequate flexibility.

### Glidant

Glidants like Talc, Micronized amorphous silica and Glycerol Monostearate facilitates spray application to the cores.

### Pigments

Opaque white or colored coating can be obtained by adding pigments like Iron Oxide and Lakes.

### Solvents For Non Aqueous Base

Isopropyl alcohol and acetone, containing small amount of water

## PACKAGING:


Aqueous Dispersion: 60 kg net in HDPE carboy.

Powder/ Granules: 10 kg net in paper fiber drum with polyethylene lining.

Organic Solution: 25kg net in DRUM.

## STORAGE:

Store at controlled room temperature. (USP, General Monograph)



Environment is seldom friendly to many APIs. Environmental factors such as light, humidity and air have deleterious effect on stability of many such APIs. The shelf life of these APIs can be enhanced by protecting them against these environmental factors.

**DRUGCOAT** polymers belonging to E series can be of vital importance in protecting against environmental factors. By using **DRUGCOAT** E series we can improve patient compliance by taste and odor masking of unpleasant APIs.



DRUGCOAT SERIES	PHYSICAL FORM	DISSOLUTION PROPERTIES	US-DMF	FUNCTIONALITY
DRUGCOAT E 100	Granules	Dissolve up to pH 5.0 Soluble in Gastric Fluid	Available	Cationic polymer with dimethyl-aminoethyl methacrylate as a functional group
DRUGCOAT E PO	Powder			
DRUGCOAT E 12.5	Organic Solution 12.5%			

## ADVANTAGES OF DRUGCOAT E SERIES:

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- pH-dependent drug release
- Moisture Protection
- Improves patient compliance
- Protection of API from environmental factors
- Taste and Odor masking
- Higher stability
- Improve storage stability of sensitive APIs
- Lowest WVTR in its class

## ADDITIVES:

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### Plasticizer

It is recommended to add 10–20% plasticizer on dry polymer substance into the DRUGCOAT E Series Solution or Dispersion, to obtain films adequate flexibility.

### Glidant

Glidants like Talc, Micronized amorphous silica and Glycerol Monostearate facilitates spray application to the cores.

### Pigments

Opaque white or colored coating can be obtained by adding pigments like Iron Oxide and Lakes.

### Solvents

Isopropyl alcohol and acetone, also mixture of these

## PACKAGING:

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Powder/ Granules: 10 kg net in paper fiber drum with polyethylene lining.

Organic Solution: 25kg net in DRUM.

## STORAGE:

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Store at controlled room temperature. (USP, General Monograph)

## SUSTAIN RELEASE FORMULATION:

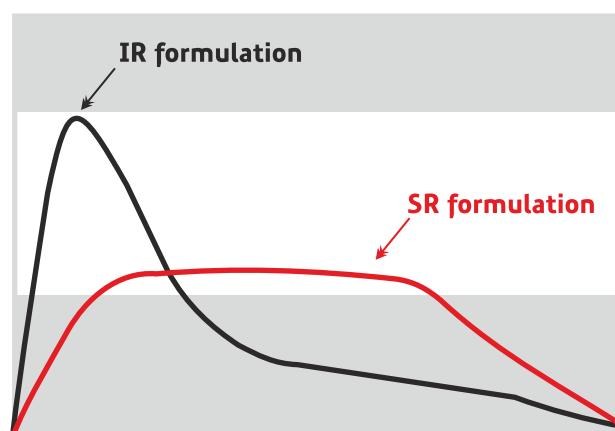
Understanding of human physiology and pathophysiology of various diseases have paved a way for development of various drug delivery system. It is now understood that the drug need not be released immediately after consumption. The sustain drug release can control the disease progression effectively.

**DRUGCOAT** polymers belonging to RL, RS and NE series can be used for time controlled drug delivery systems.

DRUGCOAT SERIES	PHYSICAL FORM	DISSOLUTION PROPERTIES	FUNCTIONALITY
DRUGCOAT RL 100	Granules	pH-independent swelling	Meth-/acrylate copolymer with trimethyl-ammonioethyl-metacrylate as functional group
DRUGCOAT RL PO	Powder		
DRUGCOAT RL12.5	Organic Solution 12.5%		
DRUGCOAT RS 100	Granules		
DRUGCOAT RS PO	Powder		
DRUGCOAT RS 12.5	Organic Solution 12.5%		
DRUGCOAT NE 30D	Aqueous Dispersion 30%		Neutral polymer of meth-/acrylates

## ADVANTAGES OF SUSTAIN RELEASE FORMULATION

- For Sustain Release of APIs.
- Customized release profiles
- Prolongation of effective plasma level
- Reduction of Total Dose
- Reduce risk of dose dumping
- Reduce toxicological effects of APIs
- Reduction of Administration frequency
- Increase patient compliance



## PACKAGING:


Aqueous Dispersion: 60 kg net in HDPE carboy.

Powder/ Granules: 10 kg net in paper fiber drum with polyethylene lining.

Organic Solution: 25kg net in DRUM.

## STORAGE:

Store at controlled room temperature. (USP, General Monograph)



Research - Investigative activities that a business chooses to conduct with the intention of making a discovery that can either lead to the development of new products or processes, or to improvement of existing products or processes. Research and development is one of the means by which business can experience future growth through developing new products or processes to improve or expand their operations.

## Research & Development

- ↻ The company has invested large amount of money and manpower resources in its R&D and F&D center and has carried out innovative process development work.
- ↻ It has a laboratory fully equipped with high-tech advanced instruments like HPLC - Varian, GPC - Varian, FTIR - Varian, GC - Varian, KF titrator, Brookfield Viscometer LV/HA, Photo spectrometer, Incubator, Dissolution tester, Disintegration tester, Autoclave, stability chamber, and other routine instruments, and highly qualified technical manpower.
- ↻ Vikram Thermo (India) Limited have a strong R&D and F&D team, with vast experienced and qualified pharmacists, research scientist, chemist & chemical engineers to develop various polymers in pharma/cosmetic applications.
- ↻ Vikram Thermo (India) Limited has also developed a separate Application/F&D facility for committed front line & back office techno marketing team to serve our customer 24 X 7.
- ↻ A newly developed advanced Wet Lab, Instrument Lab & Micro Lab to support process development & application.



## OUR CREDENTIALS

Company has state of the art manufacturing facility certified with International EXCiPACT GMP certificate, A combine certificate of IPEC EUROPE and IPEC USA for manufacturing International standard pharma Polymers (EXCIPIENTS). EXCiPACT, Good Manufacturing Practice, ISO 9001:2008 and Halal certificate and many multinational company audit approval enabling pharmacopeial GMP quality product manufacturing in India. Vikram Thermo (India) Limited also filed US-DMF for its products.



EXCiPACT GMP Certified



US-DMF Available



ISO 9001:2015 Certified



HALAL Certified



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We always in new *Re* search



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