



An Official Newsletter of the Bombay College of Pharmacy Alumni Association

## Issue 1

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#### Dear Readers,

As we step into the new year, I am excited to connect with all of you once again through this edition of our Alumni newsletter. This month, we focus on a vital yet often overlooked component in the pharmaceutical industry—**Excipients**.



While active pharmaceutical ingredients (APIs) tend to steal the spotlight, excipients play an equally crucial role in

ensuring the safety, efficacy, and stability of pharmaceutical products. These inert substances, which include binders, fillers, solubilizers, coating polymers, preservatives, and flavoring agents, are the unsung heroes that make drug formulations practical and patient-friendly. Without excipients, many APIs would fail to deliver their intended benefits.

From facilitating drug absorption to enhancing shelf life, excipients ensure that medications perform as expected, providing patients with safe and effective treatments. Furthermore, with the growing focus on patient-centric care, excipients have evolved to cater to specific needs, such as improving taste, enhancing stability, or enabling targeted delivery systems. Advances in excipient technology are also crucial in the development of biologics, personalized medicine, and innovative delivery methods.

As pharmacists, researchers, and professionals in the pharmaceutical industry, understanding excipients' role gives us a holistic perspective on drug development and opens new avenues for innovation. There are many from BCP alumni who have specialized themselves in Excipient research as well as sales and marketing.

This month we bring to you some articles contributed by the alumni in this field, I encourage you all to delve deeper into the fascinating world of excipients, reflect on their significance, and consider how they contribute to the development and regulatory sciences in pharmaceuticals.

This newsletter is dedicated to our dear Professor Dr H L Bhalla, who left us on 21st October 2024. His profound contributions to academia especially BCP

as the head of the pharmaceutics and industrial pharmacy department for many years , his unwavering dedication his students, have left an indelible mark on all who knew him. Professor Bhalla, has been a BCP stalwart, a remarkable educator, and a guide and mentor to many students like me, whose wisdom and kindness inspired us to be good humans.

Wish you all a very happy and a prosperous year ahead!

Dr Amita Karnik,
President
BCP Alumni Association.



## **Polymeric Excipients in Pharmaceutical Coatings**

Polymers and polymeric excipients play a vital role in pharmaceuticals, serving various functions that enhance drug delivery, stability, and patient compliance.

Following are some key applications of polymers in the pharmaceutical industry:

- Controlled Release Systems: Polymers are used to develop systems that
  control the release rate of active pharmaceutical ingredients (APIs). This
  can include sustained-release, delayed-release, or targeted-release
  formulations, improving therapeutic efficacy and reducing dosing
  frequency.
- 2. **Drug Delivery Vehicles**: Polymers can form nanoparticles, micelles, and hydrogels that encapsulate drugs, improving solubility, stability, and bioavailability. They can also facilitate targeted delivery to specific tissues or cells.
- 3. **Coatings**: As mentioned earlier, polymers are used in coatings for tablets and capsules to achieve taste masking, enteric protection, and aesthetic purposes. Coatings can also protect APIs from environmental degradation.
- 4. **Stabilizers**: Polymers can stabilize formulations by preventing the aggregation of proteins or other sensitive molecules, maintaining the integrity and efficacy of the drug.
- 5. **Binders and Fillers**: In solid dosage forms, polymers act as binders to hold the ingredients together and as fillers to provide bulk.
- 6. **Bio adhesives**: Certain polymers can adhere to biological tissues, which is useful in developing mucoadhesive drug delivery systems that prolong the residence time of the drug at the site of absorption.
- 7. **Biodegradable Implants**: Polymers like polylactic acid and polyglycolic acid are used in the development of biodegradable implants and devices that gradually release drugs as they degrade.

Some commonly used polymers in pharmaceuticals include:

- **Cellulose Derivatives**: Such as hydroxypropyl methylcellulose and microcrystalline cellulose, used in tablets and capsules.
- **Polyethylene Glycol**: Used as a solvent, plasticizer, or in drug delivery systems.
- Polyvinylpyrrolidone: Used as a binder and solubilizer.
- Acrylic Polymers: Used in enteric coatings and controlled-release formulations.
- Alginate and Chitosan: Natural polymers used in drug delivery and wound healing applications.

These polymers are selected based on their properties, compatibility with APIs, and the specific requirements of the drug formulation.

The polymeric excipients have several functional applications in the development of pharmaceutical dosage form, this article covers the polymeric materials used in functional coating application in pharmaceutical formulations.

#### Polymeric coating applications in Pharmaceuticals:

The coating is defined as a procedure in which the desired dosage form may be a granule or tablet coated with an outer dry film to obtain specific objectives such as masking taste or protecting against environmental conditions or modifying the release. The coating material may be composed of a film forming polymer, coloring materials, flavorants, gums, resins, waxes, plasticizers, and a polyhydric alcohol. In the modern era, polymers and polysaccharides were principally used as coating materials along with other excipients like plasticizers and pigments.

Coating polymers play a crucial role in the pharmaceutical industry, particularly in the formulation of oral dosage forms like tablets, pellets and capsules. They are used to achieve various functional and aesthetic purposes, such as:

- Controlled Release: Coating polymers can be used to control the release rate of the active pharmaceutical ingredient (API) from the dosage form. This can be in the form of sustained-release, delayed-release, or targeted-release formulations.
- 2. **Taste Masking**: Some APIs have an unpleasant taste, and coating polymers can help mask this taste, improving patient compliance.

- 3. **Protection**: Coatings can protect the API from environmental factors such as moisture, light, and oxygen, which might otherwise degrade the drug.
- 4. **Enteric Coating**: These coatings prevent the release of the drug in the acidic environment of the stomach, allowing it to be released in the more neutral pH of the intestines. This is important for drugs that can be inactivated/ degraded by stomach acid or that can irritate the gastric lining.
- 5. **Aesthetic and Branding**: Coatings can improve the appearance of tablets and capsules, making them more appealing to consumers. They can also be used to differentiate products through color and texture.

By composition coatings can be divided into two types such as:

- ✓ Film formers
- ✓ Formulated coatings

#### **Film Formers:**

Film forming coating polymers used to form coating films on oral solid pharmaceuticals and are supplied either in powder form or as dispersions. Based on the requirement the formulator has to use various other ingredients to prepare the final coating dispersion. The film farmers that are typically used include Hydroxypropyl methyl cellulose (HPMCs), Polymethacrylates (PMAs), Ethyl cellulose (ECs), Cellulose acetate phthalate (CAP), Polyvinyl alcohol (PVA), and other cellulose derivatives. Most widely used HPMC is primarily utilised in instant release coatings that are intended for aesthetic purposes. However, in combination with other polymers such as methyl cellulose they are also used for controlled or modified release. Other polymers like PMAs enable pH dependent drug delivery. CAP is primarily used in the enteric coating of tablets or capsules. PVA is a white, odourless, water soluble synthetic polymer utilised in instant release coatings. EC is a non toxic, stable, inert hydrophobic polymer that is widely used as a film former to form sustained release coatings.

Film formers are used in a wide variety of different release profiles such as immediate or instant release, enteric release, and sustained release. Instant release coatings are the leading type coatings, used in pharmaceutical oral solid dosage forms, HPMC is widely used instant release coatings specially in complex and stable formulations. Enteric release is the second largest functionality of film former coatings worldwide. PMA and CAP are primarily

used in enteric coatings. PMAs have variable solubility pH range which is manipulated to form tablet coatings that dissolve in different parts of the intestinal tract and is a key to the formation of enteric coatings. Hydroxypropyl methyl cellulose phthalate (HPMCP) and Hydroxypropyl methyl cellulose acetate succinate (HPMCAS) are also used for enteric coatings. The demand of enteric coatings is on the rise, due to their increasing use in common cold, pain and fever medications.

#### **Formulated Coatings:**

These coatings provide the formulator with a ready to use solution for meeting coating requirements they also reduce the number of steps and processes required to produce the final product. These coatings are supplied in the form of ready dispersion or powder where the key ingredient is a film forming polymer with different composition based on the functional requirement of final product. Apart from film former these compositions contains plasticisers, pigments, stabilisers etc.

Immediate release: HPMC is the most widely used polymer worldwide. It is available in variety of viscosity grades for formulated coatings. It is relatively less expensive, very flexible, highly resistant to heat, light and moisture and has no taste and odour. While HPMC is most often used for instant release drug deliveries it does not offer moisture protection. Many formulators combine it with other chemistries such as cellulose esters and cellulose acetate to achieve hydrophobicity.

**Enteric coating:** PMAs are primarily used for enteric release application . They are more expensive than HPMC. Polymethacrylates coatings face competition from HPMCP and HPMCAS, which are also effective film formers that are used in enteric coating application. HPMCP and HPMCAS offer excellent film strength and resistance to simulated gastric fluid. CAP is widely used in capsules, specifically for drug liberation in the small intestine.

**Sustained release coating:** Ethyl cellulose is the primary polymer based used in these coatings.

These polymers are selected based on the specific requirements of the drug formulation, including the desired release profile, stability, and compatibility with the API and other excipients.

#### Major players in film formers market:

Suppliers	Trade Name	Polymer	Application
Eastman	Eastman CAP NF CA 398 10NF CAB 171-15	CAP Cellulose acetate Cellulose acetate butyrate	Enteric SR SR
Evonik	Eudragit L, S, FS Eudragit RL, RS, NE, NM Eudragit E	Polymethacrylates	Enteric SR Protective
IFF	Aquacoat CPD Aquacoat ECD	CAP EC	Enteric SR
JRS	Vivapharm HPMC E5/6/15	HPMC	IR
Lotte Fine Chemical	AnyCoat-C AnyCoat-P	HPMC HPMCP	Instant release Enteric
Roquette	Lycoat	Modified hydroxypropyl starch	IR
Shin-Etsu	Pharmacoat 603/645/606/615 Aqoat HPMCP 50/55/555	HPMC HPMCAS HPMCP	IR Enteric Enteric

#### **Other Coating Additives:**

#### Plasticizers

These are low molecular materials that were added to enhance the mechanical strength of a polymers. Plasticizers weaken the intermolecular forces of the polymers, thereby reducing their rigidity and improving their coalescence properties while making films. They can reduce the glass transition temperature of amorphous polymers, decrease the interactions of different polymers, and reduce the brittleness of films. They alter the plasticity of filmforming polymers (FFP) in two basic ways, external and internal plasticizing. External plasticizing involves the use of plasticizers, while internal plasticizing appears to be due to a modification in chemical structure that ultimately changes its physical properties. External or internal plasticizers were used in an optimum range, which ranges from 1–50%, but most commonly 10% plasticizers were used. Polyethylene glycol and HPMC were the polymers most commonly and effectively used. Triacetin, a less commonly used plasticizer, protects the aqueous coating by creating a moisture barrier against the coat and protects the formulation.

#### Colorants and Opacifiers

To improve product identification, enhance the appearance of products, and decrease the risk of counterfeit products, colorants were added to the formulations. Opacifiers were used in those products that were damaged by light. The ideal concentration of colorants used in film coating formulations (FCF) ranges from more than 2% w/w for dark shade and 0.01% w/w for light

shade. Each country has its own regulatory approved opacifiers and colorants. Colorants may be water-insoluble, known as pigments, and water-soluble colorants, known as dyes.

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Author: Dr. Agnivesh Shrivastava, completed B. Pharm. from IPS Academy Indore; M. Pharm. and Ph.D. (Tech.) in Pharmaceutics from the Bombay College of Pharmacy, Mumbai. He has work experience of over 15 years in multinational companies like GlaxoSmithKline, Pfizer Pharmaceuticals, Sun Pharma Advance Research Company, Gattefosse. Since 2022, he is working with Evonik as Head, formulation RD&I. He has expertise on processes and techniques involved in oral solid dosage forms, topical drug delivery and noninvasive advanced drug delivery. He has published multiple research papers, book chapters and

meeting abstracts related to formulation development and drug delivery. He is associated with various academic institutes as referee for masters and PhD thesis.



### Chai Pe Charcha | September 2024



September 21st,2024 | Venue: BCP Seminar Hall

On the 21st of September 2024, the BCP Alumni Association organised an insightful alumni meet, bringing together current students and alumni to foster connections and provide valuable insights into career opportunities in the pharmaceutical industry.



The event began with the introduction of Mrs. Lorna Pinto, Assistant Commissioner, who shared her extensive experience and knowledge of the Maharashtra Food and Drug Administration (FDA). She provided a detailed overview of the FDA's structure, responsibilities, and the regulatory committees that play crucial roles in the regulation of drugs and cosmetics, such as the Drugs Technical Advisory Board (DTAB), Drugs Consultative

Committee (DCC), and Central Drug Standard Control Organisation (CDSCO).

Mrs. Pinto also elaborated on the role of a Drug Inspector, including the qualifications required, their responsibilities, powers, and career progression opportunities within the FDA, both at the state and central levels. She further

captivated the audience with stories of the cases she handled, showcasing the dynamic and challenging nature of her work as an Assistant Commissioner(drugs) FDA.



The alumni meet included an engaging Q&A session, where students asked a range of questions on topics such as the difference between state and central level DIs, the recruitment process, and the challenges faced during inspections.

Alumni shared their experiences as well, especially their interactions with both Indian and US FDA inspections, which provided students with practical perspectives on regulatory processes and their impact on the industry. Their input was both informative and eye-opening for students who were eager to understand real-world industry scenarios.



The event concluded with a vote of thanks delivered by Mr. Ashish Babtiwale, followed by the felicitation of Mrs. Lorna Pinto with a sapling and a cup as a memento. The alumni then introduced themselves, reminiscing about their time at BCP, sharing how the college helped shape their careers, and expressing their eagerness to support the student community

through more workshops and seminars in the future.

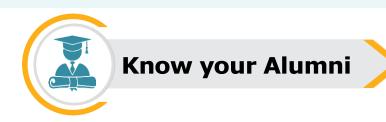
The meet ended on a positive note with the distribution of refreshments to alumni and students, marking the close of an insightful and enriching alumni meet.

## Chai Pe Charcha | December 2024

In the Chai pe Charcha session on 21st December 2024, Dr. Agnivesh Shrivastava has guided students at Bombay College of Pharmacy on career in Pharmacy. In his talk he covered various career prospects and their pros and cons along with the path to achieve success. He also covered suitability of job based on the qualifications which was helpful to the students to overcome dilemma of career in pharma domain. Here are some glimpses of his interaction with the students during Chai Pe Charcha.



December 21st,2024 | Venue: BCP Seminar Hall



## Professional journeys with a personal touch!

Ft. Yash Jalundhwala (BPharm 2007) & Dimple Modi (BPharm 2009)

The formative years spent at BCP have a lasting impression and impact on all students. The shared experience of the BCP journey strengthens the bond which connects our global BCP Community. Some elements unique to the journey at BCP that come to mind could include: (i) influence of the lush green gardens and open spaces on nurturing an open and curious minds; (ii) ability to see chemistry coming to life — both through the experiments in the laboratories and in the life-long camaraderie between individuals; (iii) batches uniting with an intense collaboration to win coveted trophies but also not shying away from engaging in a competitive banter to reign supreme during college days; (iv) celebrating traditional festivals, college milestones and ensuring robustness of a system which promotes sharing of knowledge and experiences across the years. The list is not even exhaustive but certainly would have already taken us all down a nostalgia trip. As demonstrated by the

journeys of many of our alumni, key elements of the BCP life transcend to influence development pathway and life journey itself. And ever so often, the relationships flourish

and grow to stronger partnerships at workplace and/or in life itself. Today, we will take you through the journey of one such couple, Yash J. Jalundhwala (B.Pharm 2007) and Dimple A. Modi (B.Pharm 2009), and sharing their reflections on the time at BCP.

#### Journeys So Far ...!

Yash currently serves as Senior Director, Global Market Access and Pricing at Moderna (Cambridge, USA) supporting commercial and global launch strategies for respiratory vaccines. He is also an Adjunct Assistant Professor of Pharmaceutical Policy at the University of Illinois at Chicago (Chicago, USA). He has previously served in variety of leadership roles in Global Market Access and Pricing and Global Health Economics and Outcomes Research groups at

AbbVie (North Chicago, USA) going across the product life-cycle supporting the development, launch and commercialization of innovative medications in the areas of Neuroscience, Infectious Disease and Cardiology. After graduating from BCP, Yash earned a Masters in Pharmacy Administration (2010) and a Doctorate degree in Pharmacy Systems, Outcomes and Policy (2016) both from the University of Illinois at Chicago (Chicago, USA).

Dimple currently serves as Director, Precision Medicine at Regeneron (Tarrytown, USA) where she leads the development and execution of biomarker strategies for development of new oncology treatments and subsequent indication expansion. Prior to her work at Regeneron, Dimple served in a variety of leadership roles at AbbVie (North Chicago, USA) in Translational Medicine as well as Search and Evaluation group. Her extensive expertise in Oncology clinical development including target validation, patient enrichment and evaluation of treatment effectiveness spans across solid tumors and hematological malignancies. After graduating from BCP, Dimple earned MS with a focus in Neuropharmacology from the University of Southern California (Los Angeles, USA) and a PhD with a focus in Cancer Biology from the University of Illinois at Chicago (Chicago, USA).

Outside of their time at BCP, both Yash and Dimple were actively involved in various activities with World Health Organization, UNESCO and International Pharmaceutical Federation, in service of strengthening the Pharmacy profession. Majority of this contribution was based on their leadership roles at the International Pharmacy Students Federation (IPSF) — Yash as the Chairperson of Public Health (2008-09) and Dimple as the Chairperson of Pharmacy Education (2010-11) amongst others. During their time in BCP, Yash and Dimple were both active in the various college and association activities. Within the BCP Student Council, Yash served as Cultural Secretary and General Secretary while Dimple served as Editor for the BCP Magazine (*Credence*). Outside of BCP, they both were active in the student activities of the Indian Pharmaceutical Association — Maharashtra State Branch (IPA-MSB) as General Secretary and Editor (*Resonance*) and in the formative steps of the IPA — Student Forum.

#### **Excerpts of their reflections from BCP**

Q: How has the time at BCP shaped your career today?

• <u>Dimple</u>: I feel an immense gratitude to the time spent at BCP as it has laid a strong foundation in my understanding of the molecular basis of diseases and treatments. I fondly recollect the many interactions with the teachers and research faculty, the practical observations and insights from the non-teaching staff and the hours of chats with peers over a *cutting chai* or in the library halls – all of which have strengthened a deep curiosity for innovation and research. The experiences and scientific foundation built during the time in BCP remain a strong driving force in my research journey and pursuit of finding innovative treatments.

**Q:** How do you reflect on the extra-curricular opportunities at BCP?

Yash: I feel very fortunate that in addition to o be able to get an exposure to deep scientific learning, I could partake in rich extracurricular activities. The participation in the activities combined with the mentoring from seniors, faculty and industry leaders honed interpersonal and leadership skills. Case in Point - It is at BCP, that I first learnt to scientific communication and presentations, skills vital in day-to-day activities till date. Similarly the opportunities to organize and participate in the many college events gave first hand experiences in competitive team-work, organizational behaviours and working in matrix organization; elements which are important in a corporate journey too. The additional opportunities to volunteer within the IPA activities gave a unique exposure to the pharmaceutical industry and pharmacy profession overall. These early exposures have played a large influence in the choices I have actively made throughout my professional journey.

Q: How did the alumni network influence your professional journey?

<u>Dimple</u>: Ever since my first year as a student, I have looked up to the alumni network for an inspiration in a relentless pursuit of scientific innovation. In particular the Women Leadership in Pharmaceutical Sciences inspired me to actively volunteer for organizing events to promote STEM (Science, Technology, Engineering and Mathematics) education in middle school girls and their families, particularly those coming from under-represented and under-privileged backgrounds. I

thank the alumni network members for their openness and mentoring and I certainly aim to paying it forward.

• Yash: I was intrigued by the opportunity of graduate education in the area of health economics and outcomes research (HEOR). As a relatively newer field, I was apprehensive about the research journey itself and the career prospects overall. It is largely thanks to the openness of the individuals in the BCP alumni network that my interests converted into a pursuit and led to me to start my professional journey. Ever since, I have leaned on the alumni network throughout various stages of career development to learn from their experiences. I do not think navigating this journey could have been as easy without the strong support from the alumni in the field.

Q: Can you share any fun memory from your time in BCP?

- <u>Dimple</u>: One of my fond memories at BCP is the time spent in the cafeteria, particularly around the Table Tennis (TT) area. Not only did it become a great way to enjoy a sport I used to already like, it also formed a great way to build friendships. Be it waiting for your turn, or playing or simply watching others play, the TT area become a great way to unwind after a long day in labs or to get that quick stress buster effect before an exam. The games may have been forgotten but the friendships and memories built in the cafeteria/ TT tables will be cherished for a very long time.
- Yash: During our time at BCP, we had experienced aggravated flooding in Mumbai following a cloud burst phenomenon (July 2005). Given the rapidly elevating water levels and challenged communication and travel options, some of us hunkered down in the college itself. The teachers and staff ensured adequate food provisions and dryness to shelter from the storm. So, in the company of friends and warmth of the college, we enjoyed an experience of "camping" in the college. The support of everyone in the college afforded our families a relief of safety as we weathered past the rains.

**Q:** Can you share any memorable alumni interactions over the years?

 <u>Dimple</u>: I vividly recollect a time in Chicago when I could meet a lot of BCP alumni during the American Association of Pharmaceutical Scientists (AAPS) Annual meeting. It was amazing to see batch mates,

teachers, current students and alumni all together. Little did I know that I will have a chance to have more interactions with some of those alumni during future work/internship opportunities.

• <u>Yash</u>: One of the summers, I was fortunate to have 7 BCP alumni working together in my department across different roles including interns. It was amazing to share memories from across the years and bring the BCP energy to work together.

**Q:** What advice can you share with our students?

- <u>Dimple</u>: Stay Curious an unexplored world awaits you | Support your Community together we can go faster and further | Keep it Simple simplicity is the ultimate sophistication
- Yash: Work Hard | Stay Humble | Be Kind | Have Fun ☺

#### **LinkedIn Profiles:**

- Yash Jalundhwala <a href="https://www.linkedin.com/in/yash-jalundhwala/">https://www.linkedin.com/in/yash-jalundhwala/</a>
- Dimple Modi https://www.linkedin.com/in/dimplemodi/

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I can cure your pain, but I'm not a doctor
o Answer:
I'm the sweet solution to your sugar highs and lows, coming in all sorts of acting styles – rapid, short, intermediate, and long.
o Answer:
I'm the calm in the storm of high blood pressure, available in tablet and extended-release forms. I'm here to keep things cool and collected.
o Answer:
I'm a medication you use when you sneeze and become all red.
o Answer:
I'm a tiny tablet that dissolves under your tongue, often used for quick relief.
o Answer:
I'm the bacteria's worst nightmare, available in tablets, capsules, and even liquid form. I'm here to make sure those pesky infections don't stand a chance.
o Answer:

7.	I'm the puff of fresh air you need when your lungs are throwing a tantrum. I come in handy when you're feeling a bit breathless.
	o Answer:
8.	I'm a common pain reliever, often found in your medicine cabinet.
	o Answer:
9.	I'm the cholesterol buster that keeps your heart happy. You can pop me in tablet form, and I'll do the rest.
	in tablet form, and i ii do the rest.
	o Answer:
10	a bon fire.
	o Answer:
Solut	ion <sup>.</sup>
1.	Medicine
2.	Insulin
3.	Beta-Blocker
4.	Antihistamine
5.	Sublingual tablet
6.	Antibiotic
7.	Inhaler
8.	Ibuprofen
9.	Statin
10	Antacid