## THE PHARMA CHEMICALS AND EXCIPIENTS

# Major Global Trends in Oral Solid Dosage Form Excipients

Sustainability has less of an impact in pharmaceutical chemicals, but Asia remains a key growth area in this segment. Oral Solid Dosage Forms remain the most important segment, even if their position is challenged by the emergence of large molecules (and notably biologics) that are difficult to formulate into an OSDF product.

DIRECT COMPRESSION TABLETS

Tablets continue to be the most preferred form of OSDF Direct compression technique drives the demand for directly compressible excipients, such as MCC, anhydrous lactose, etc.

SI

Orally Disintegrating Tablets drives the consumption of superdisintengrants such as crospovidone and CCS, as well diluents providing good mouthfeel such as polyols

SOLUBILITY ENHANCEMENT

Poorly soluble drugs, and advancements in bioavailability enhancement technologies gives rise to demand of solubility enhacement excipients, including polymer and lipid carriers

POTENCY

Increasing number of high potency APIs gives rise to capsule formulations

SOFT GELS

HIGH

Rise in soft gel capsules drives lipid excipients and polyols





# Growing Opportunities in Biologics

While the OSDF segment has traditionally been (by far) the largest share of pharmaceutical production, it is in biological pharmaceuticals that the growth is the strongest nowadays.

Biologics drug development is an impending opportunity for ingredient suppliers, especially because specialty ingredients are required in not only the formulation of the biologic drugs but also in their production, starting from the upstream cell culture in bioreactors, followed by downstream processing, pre-formulation of the drug, and, finally, the fill-finish. While excipients are mainly used in the later stages of formulation and fill-finish, there is a wide range of bioprocessing ingredients essential to the upstream and downstream stages.

The biopharmaceutical industry is expected to witness a global growth of 10% to 12% over the next five years in terms of the number of biologic drugs including novel biologics, biosimilars, and bio-betters.

The highest growth in terms of number of drugs is expected for monoclonal antibodies (mAbs), with a CAGR of more than 15% over the coming years. The number of biological vaccines and hormones is also expected to grow at strong rates of 8% to 10%, and 4% to 7%, respectively.

The demand for bioprocessing ingredients is currently dominated by the cell culture ingredients and supplements category. The category is expected to grow at an above-market CAGR of around 10% between 2018 and 2023. Moreover, the consumption of fill-finish and pre-formulation excipients is expected to increase at a high rate with the growth of biologics production.

The consumption of biologic excipients is forecast to grow at an average annual rate of 8% to 9% in the next five years. Carbohydrates, polymers, and amino acids are among the particularly fast-growing ingredient groups in this industry.

#### **BIOPHARMACEUTICAL TECHNOLOGY TRENDS**



### MONOCLONAL ANTIBODIES:

This are antibodies that are produced from identical immune cells that are all clones of a unique parent cell.



#### **VACCINES:**

When molecular biology techniques are used during the production of a vaccine, it can be considered as a biopharmaceutical.



#### **HORMONES:**

They belong to the class of signaling molecules that are produced by various glands in any multicellular organism.



## GROWTH FACTORS:

Are the signaling molecules between cells. They are responsible for stimulating cellular growth, proliferation, healing, and cellular differentiation.



#### **ENZYMES**

Are catalyst protein molecules in cells, which brings about almost all the chemical reactions required for the sustenance of living organisms.



#### **BLOOD PRODUCTS:**

Can be broadly classified into two categories: fractioned plasma products, and blood grouping and phenotyping reagents.



#### **CONJUGATES:**

Are made of a protein bound with another protein, peptide, sugar, or drug molecule; it's made with an antibody and a drug, or antibody-drug conjugates (ADCs), are the most common.



#### RECOMBINANT PROTEINS

Products considered under the scope of recombinant proteins include blood factors, interferons, fusion proteins, thrombolytic agents, interleukin-based products, tumor necrosis factors, and other products, which are not separately classified in the above-mentioned classes.





## Sensation Bringing Topicals Create Opportunities

Topical drug delivery continues to gain importance in the pharma industry because it offers several advantages, including ease of self-administration, avoidance of first-pass effect, and prolonged duration of action.

Topicals are also targeted, rather than systemic, and they are delivered to localized sites and are therefore safer for, for example, infants or the elderly.

Under consumer demand, the topical pharmaceutical formulators are pressed for bringing in better sensory benefits in topical products and thus select excipients that offer these characteristics.

Several topical pharmaceutical formulations, notably those used for acne treatment, will tend to offer greater cosmetic or aesthetic features. An aesthetically pleasant product is more likely to have patient acceptance. This feature also helps formulators differentiate their products in the competitive topical pharmaceutical market.

Natural excipients or excipients derived from natural sources will be a major focus of attention for topical pharmaceutical formulators, as inorganic excipients are likely to face a gradual decline.

#### **TECHNOLOGY TRENDS: CONSUMER TRENDS:** Gels and creams Increasing cases of skin disorders Transdermals Nasal sprays, eye and ear drops **TOPICAL** Increasing demand for self-administration and home healthcare **PHARMA** Upcoming technologies: devices Liposomes **TRENDS** Solid lipid nanoparticles Growing demand for better touch Micro-needles and feel experience during the Microspheres application of topical formulations Nanoemulsion Nanoencapsulation **EXCIPIENTS TRENDS:** Excipients suited for enhancing sensory aspects of the formulation growing in demand Natural excipients or excipients derived from natural sources is a major focus of attention Different excipient chemistries compete in a category based on price





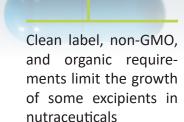
# Growing Importance of Dietary Supplements Drives Excipients in Nutraceutical Space

Consumer compliance and convenience giving rise to novel dosage formats, such as gummies, chewables, ODTs, etc., leading to growing use of different types of excipients in nutraceuticals

Preference of direct compression technology over wet granulation for tablet manufacturing favors directly compressible excipients. Upcoming ban on titanium dioxide in France is driving the use of few excipients, such as calcium carbonate and HPMC

2019

2024



Growing price competition in the nutraceutical markets restrict the use of high-priced excipients

US and Europe face competition from imports of some nutraceutical excipients

**CAGR +4-5%** 



