Trends in Oral Solid Dosage Forms: Review of 2024 EMA Approvals

Background

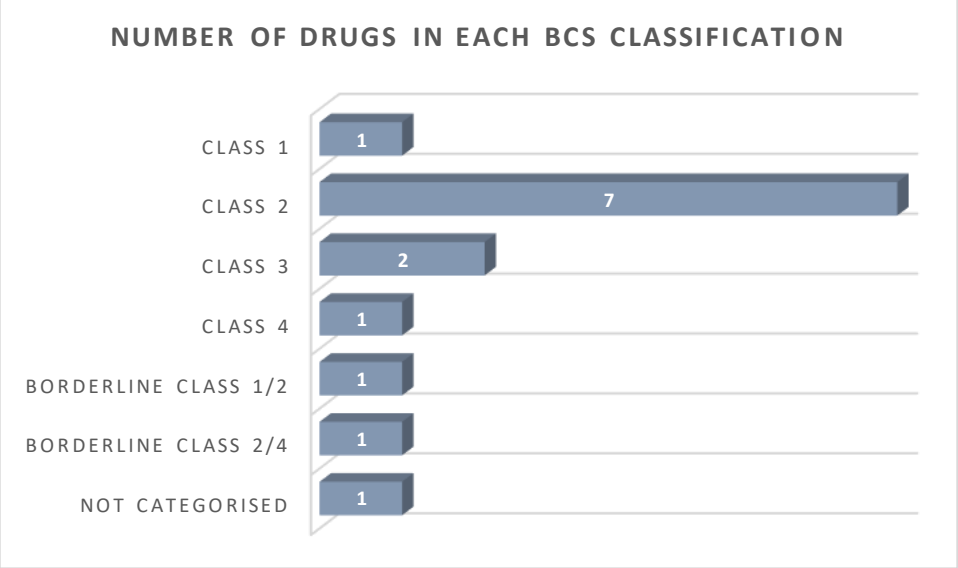
This document is an overview of NCEs approved by the European Medicines Agency in 2024 as oral solid dosage forms and provides an insight into current formulation development and manufacturing strategies. The primary data source is EPAR documentation, which can be found on the EMA website. Fourteen NCEs approved by the EMA in 2024 were in the form of orally administered solid dosage forms.

Drug Substance

Four of the fourteen NCEs are in the form of salts, comprising: Hydrochloride (2); mesilate (1); and lysine (1).

The average molecular weight (non-salt form) is 455 g/mol (range 355-593).

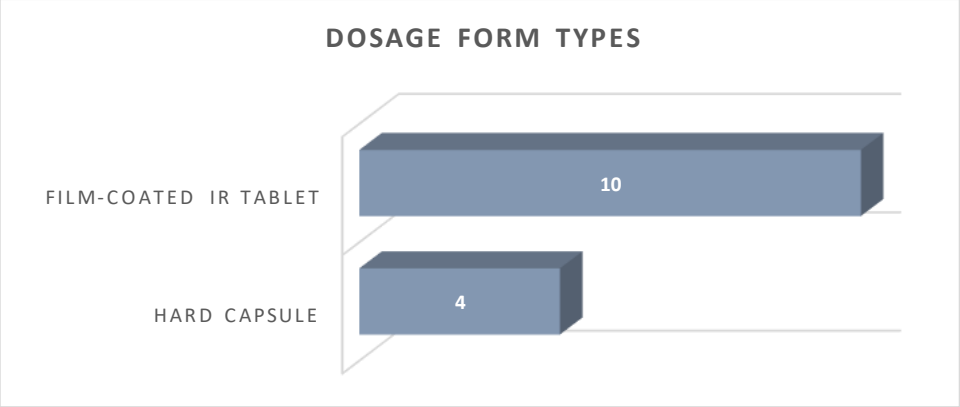
The BCS Classification is disclosed for thirteen of the fourteen NCEs; the most common classification is Class 2.



Across the fourteen NCEs, there are 23 different approved dosage form strengths, with an average value of 106 mg (range 1-400).

Dosage form types

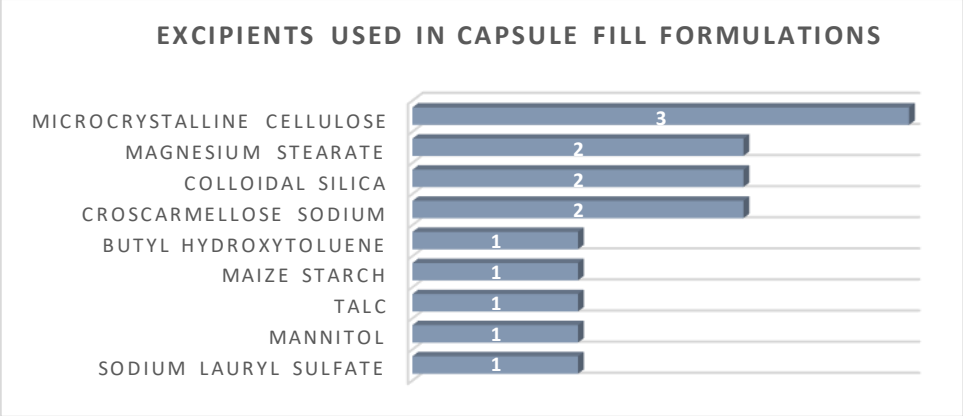
Film-coated immediate release tablets are the dosage form for ten of the NCEs. The remaining four NCEs are formulated as hard capsules containing a solid fill.



Excipients

- ***Capsules***

Excipients used in the four capsule fill formulations are displayed below. All formulations use a gelatin shell.

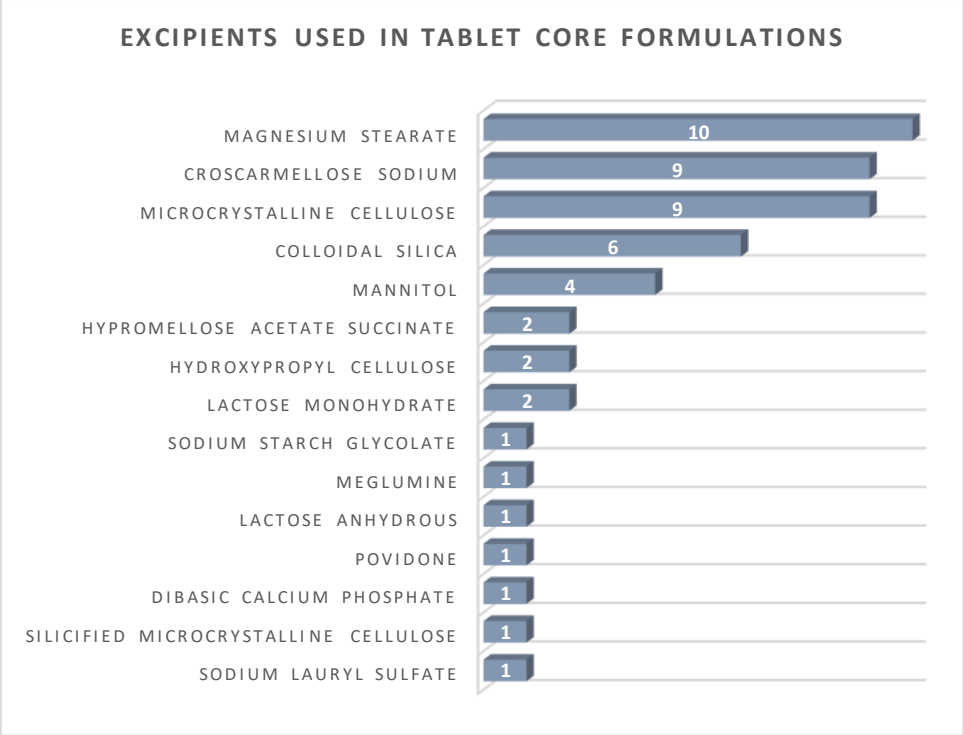


Butyl hydroxytoluene is included as a stabilizer in one of the formulations where the drug is prone to oxidation.

One product (FABHALTA™) is excipient-free and comprises 200 mg of drug substance (BCS Class 3) filled into the capsule shell.

- ***Tablets***

Excipients used in the ten tablet core formulations are presented in the chart below. Magnesium stearate, microcrystalline cellulose and croscarmellose sodium are the three most widely used excipients and appear in at least nine of the products.



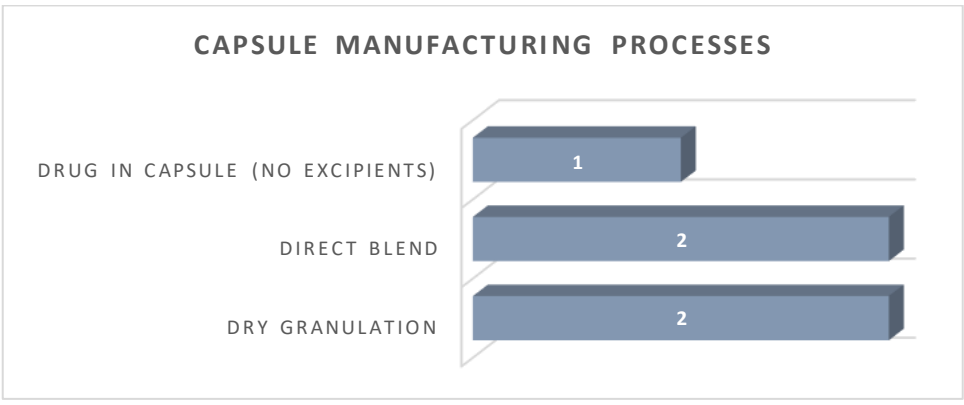
Note: "Colloidal silica" encompasses hydrated, anhydrous and hydrophobic forms

The tablet film coatings are based on polyvinyl alcohol (eight products) and hypromellose (two products).

Manufacturing processes

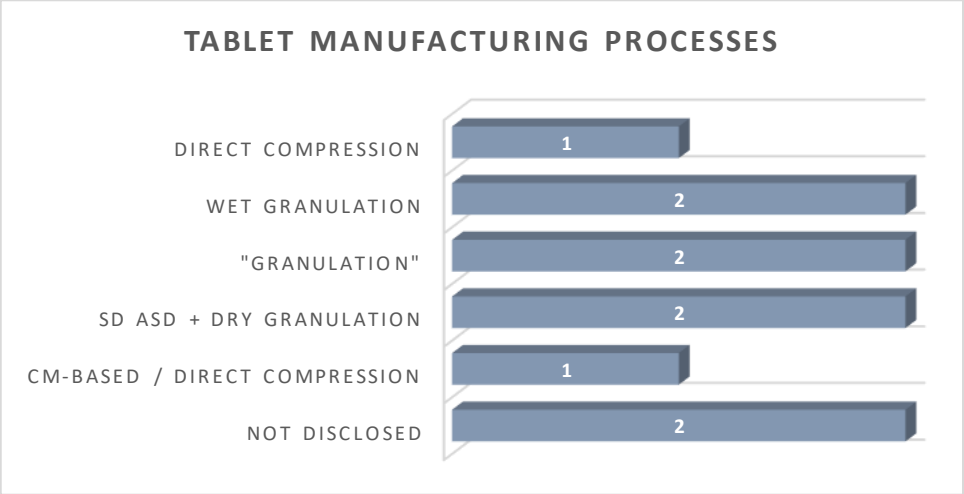
- ***Capsules***

The processes used for preparing the capsule fill are summarised below. It should be noted that although there are only four capsule products, the sum of the processes in the chart is five. This is because two processes are described for one of the products (AUGTYRO™): 40 mg capsules are made using direct blending whereas 160 mg capsules are made using dry granulation.



- ***Tablets***

The processes used for preparing the tablet cores are summarised below.



Two tablets (VOYDEYA™ and WELIREG™) contain drug in the form of an amorphous solid dispersion prepared by spray drying (SD ASD); both drugs are BCS Class 2.

One product (LAZCLUZE™) incorporates continuous manufacturing (CM) in the production process: a pre-blending step is performed in batch mode followed by final blending and direct compression in continuous mode. The tablets are then film coated in batch mode.

All remaining dosage forms are prepared using conventional processes, although limited details are provided for four of the products (categorized as *Not disclosed* or *"Granulation"*).

Summary

The majority of the oral NCEs approved by the EMA in 2024 are BCS Class 2; two of these are formulated as ASDs to enhance solubility. One product uses continuous manufacturing for some of the production steps. All the remaining dosage forms can be considered conventional in terms of manufacturing processes and excipient choice.