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

Background

This document provides an overview, from a pharmaceutics point of view, of novel drug products approved by the FDA in 2024 as oral solid dosage forms. The primary data source is the Prescribing Information for the respective products.

Twenty novel products were approved as oral solids and collectively contained 24 active ingredients: one product contained three active ingredients, and two products contained two active ingredients.

Product overview

Product details are summarized in Table 1 (tablets), 2 (hard capsules) and 3 (softgel). Tablets are the principal dosage form (14 products): all are immediate release and film coated. There are 5 hard capsules and 1 softgel.

One of the formulations (ORLYNVAH) is a bilayer tablet.

In COBENFY capsules, the two active ingredients are formulated as separate pellets, presumably to allow easy adjustment of dose during filling, since the dose ratio of the two active ingredients is different across the three capsule strengths.

Drug substance

Nine of the 24 active ingredients are in the form of salts, and one is in the form of a co-crystal. The salts are hydrochloride (2 compounds); mesylate (1); citrate (2); phosphate (1); tartrate (1); lysine (1); and calcium (1).

The average drug molecular weight (free acid/base) is 439 g/mol (range 281-655 g/mol).

Dose strength

Across the 24 products, there are 45 different dose units, with an average strength of 108 mg (range 3-500 mg).

Table 1. Details of tablet formulations

Proprietary name	Active ingredient(s)	MW	Strength(s)	Excipients (core / capsule fill)	Film coating polymer(s)
ALYFTREK	Vanzacaftor	655 (Ca dihydrate)	4 and 10 mg	Croscarmellose sodium, hypromellose, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate	Hypromellose, hydroxypropyl cellulose
	Tezacaftor	520	20 and 50 mg		
	Deutivacaftor	402	50 and 125 mg		
ATTRUBY	Acoramidis	329 (HCl)	356 mg	Croscarmellose sodium, magnesium stearate, microcrystalline cellulose, silicon dioxide	Hypromellose, polyvinyl alcohol, vinyl alcohol graft copolymer
IQIRVO	Elafibranor	384	80 mg	Colloidal silica dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and povidone	Polyvinyl alcohol
ITOVEBI	Inavolisib	407	3, 9 mg	Lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate	Polyvinyl alcohol
LAZCLUZE	Lazertinib	669 (mesylate hydrate)	80, 240 mg	Croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and silica hydrophobic colloidal	Polyvinyl alcohol
LEQSELVI	Deuruxolitinib	412 (phosphate)	8 mg	Colloidal silicon dioxide, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and povidone	Polyvinyl alcohol
OJEMDA	Tovorafenib	506	100 mg	Copovidone, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose	"Opadry Orange"
ORLYNVAH	Sulopenem etzadroxil	478	500 mg	Croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose	Polyvinyl alcohol
	Probenecid	285	500 mg		
REVUFORJ	Revumenib	841 (citrate hydrate)	25, 110, 160 mg	Microcrystalline cellulose, dicalcium phosphate, crospovidone, hypromellose, sodium bicarbonate, hydrophobic colloidal silica, magnesium stearate	Polyvinyl alcohol
REZDIFFRA	Resmetirom	435	60, 80, 100 mg	Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, and microcrystalline cellulose	Polyvinyl alcohol
TRYVIO	Aprocitentan	546	12.5 mg	Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose	Hydroxypropyl cellulose, polyvinyl alcohol
VAFSEO	Vadadustat	307	150, 300, 450 mg	Colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate	Polyvinyl alcohol
VORANIGO	Vorasidenib	520 (hemicitric acid hemihydrate co-crystal)	10, 40 mg	Croscarmellose sodium, magnesium stearate, microcrystalline cellulose, silicified microcrystalline cellulose and sodium lauryl sulfate	Hypromellose
VOYDEYA	Danicopan	580	150 mg	Colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate	Polyvinyl alcohol

Table 2. Details of hard capsule formulations

Proprietary name	Active ingredient(s)	MW	Capsule material	Strength(s)	Excipients (capsule fill)
COBENFY	Xanomeline	432 (tartrate)	Hypromellose	50, 100, 125 mg	Xanomeline tartrate pellets contain ascorbic acid, microcrystalline cellulose, and talc
	Trospium chloride	428		20, 20, 30 mg	Trospium chloride pellets contain lactose monohydrate, microcrystalline cellulose, and talc
ENSACOVE	Ensartinib	634 (di-HCl)	Hypromellose	25, 100 mg	Microcrystalline cellulose and stearic acid
LIVDELZI	Seladelpar	627 (lysine dihydrate)	Gelatin	10 mg	Butylated hydroxytoluene, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose
MIPLYFFA	Arimoclomol	506 (citrate)	Hypromellose	47, 62, 93, 124 mg	Microcrystalline cellulose and magnesium stearate
XOLREMDI	Mavorixafor	349	Gelatin	100 mg	Colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, microcrystalline cellulose, sodium lauryl sulfate, and sodium stearyl fumarate

Table 3. Details of softgel formulation

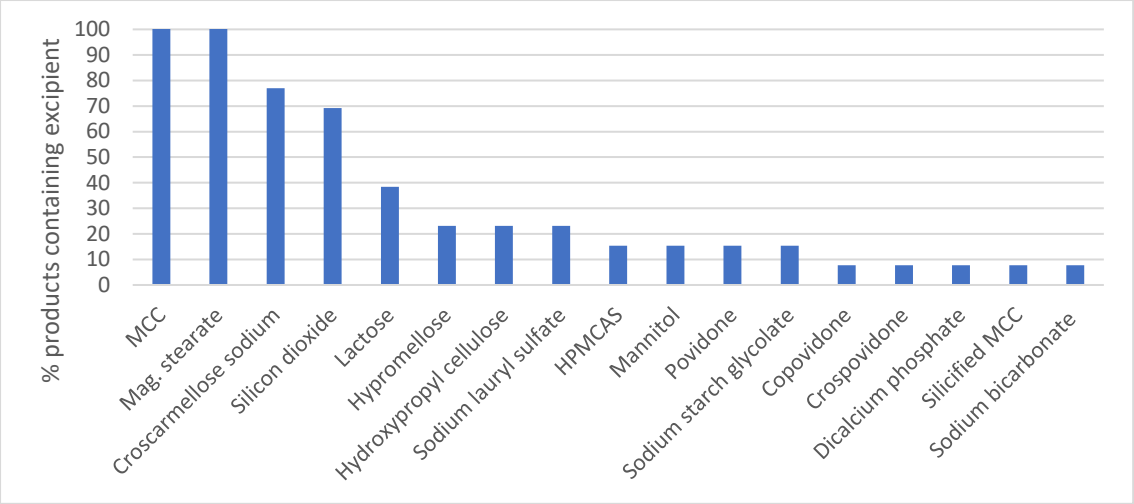
Proprietary name	Active ingredient(s)	MW	Strength(s)	Excipients (capsule fill)
CRENESSITY	Crinecerfont	483	25, 50, 100 mg	Lauroyl polyoxyl-32 glycerides, medium chain triglycerides, propylene glycol dicaprylate/dicaprate, and Vitamin E polyethylene glycol succinate

Excipients

- ***Tablets***

Excipients used in the tablet core are displayed in Figure 1. All the products contain microcrystalline cellulose (MCC) and magnesium stearate. While no manufacturing details are provided within the Prescribing Information, certain information can be inferred from the excipients used. For example, two formulations (ALYFTREK and VOYDEYA) contain hydroxypropyl methylcellulose acetate succinate (HPMCAS), and one (OJEMDA) contains copovidone: these formulations likely contain drug in the form of an amorphous solid dispersion (ASD). Indeed, the patent literature confirms a hot-melt extrusion process is used in the manufacture of OJEMDA to produce an ASD.

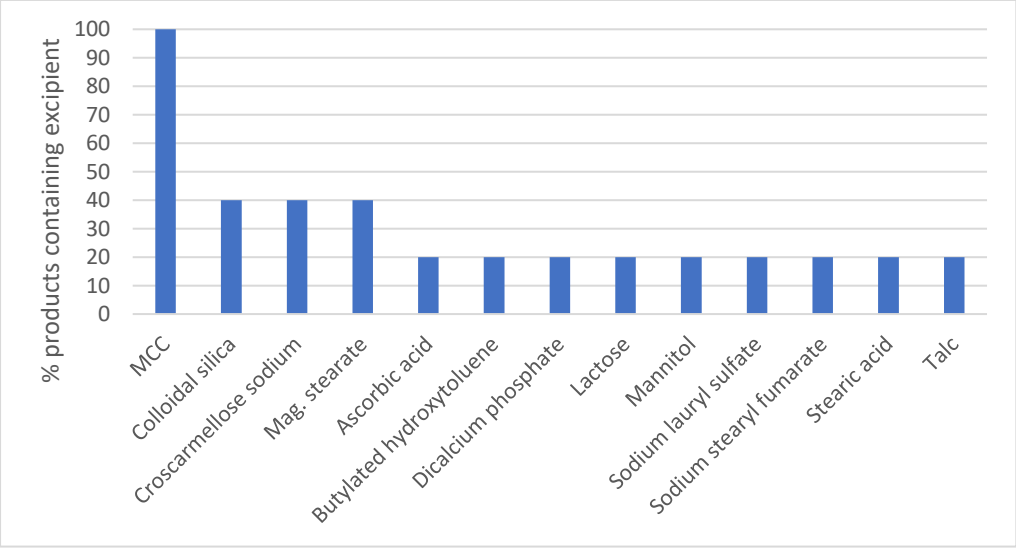
Figure 1. Excipients used in tablet formulations (core)



- ***Hard capsules***

Three of the five products use hypromellose capsule shells and the remainder use gelatin shells (Table 2). Excipients appearing in the five hard capsule fill formulations are displayed in Figure 2. As with the tablet formulations, MCC is found in all products.

Figure 2. Excipients used in hard capsule formulations (fill)



- ***Softgel***

The softgel product contains excipients consistent with a self-emulsifying drug delivery system (Table 3).

Summary

Twenty novel oral solid products were approved by FDA in 2024. Based on the information available within the reviewed documentation, fourteen of the products appeared to utilize “conventional” formulation technologies. The “non-conventional” technologies comprised: bilayer tablet (one product); ASDs (three tablet products); pellets (one capsule product); and a self-emulsifying DDS (one softgel product).