Trends in Oral Dosage Forms: Review of 2025 FDA Small Molecule Approvals

Introduction

This document provides an overview, from a pharmaceutics point of view, of novel small molecule drugs (NCEs) approved by the FDA in 2025 as oral dosage forms. The primary data source is the Prescribing Information for the respective products.

Twenty-four novel oral small molecule drug products were approved during 2025 and collectively contained 25 active ingredients: one product contained two active ingredients, and one product was approved as two formulations (hard capsule and dispersible tablet).

It should be noted that an oral formulation for semaglutide (WEGOVY) was approved in late 2025. However, the active ingredient is a 4kDa peptide and outside the scope of this review.

Product overview

Product details are summarized in Table 1 (fourteen film-coated tablets), Table 2 (six hard capsules), Table 3 (one softgel) and Table 4 (four solids for oral solution/suspension). All film-coated tablets are immediate release.

Drug substance

Six of the 25 active ingredients are in the form of salts, comprising hydrochloride/di-hydrochloride (3 compounds), mesylate (1), tosylate (1), and adipate (1).

The average drug molecular weight (free acid/base) is 471 g/mol (range 227-718 g/mol).

Dose strength

Across the 24 products there are 36 different dose units, with an average strength of 305 mg (range 0.75-3000 mg).

Table 1. Details of film-coated tablet formulations

Proprietary name	Active ingredient(s)	Mol wt (free acid / base)	Strength(s)	Excipients (core)	Coating polymer(s)
BLUJEPA	Gepotidacin mesylate dihydrate	449	750 mg	Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose	Polyvinyl alcohol
BRINSUPRI	Brensocatib monohydrate	420	10, 25 mg	Dibasic calcium phosphate dihydrate, glyceryl dibehenate, microcrystalline cellulose, silicon dioxide, and sodium starch glycolate	Polyvinyl alcohol
EKTERLY	Sebetralstat	492	300 mg	Microcrystalline cellulose, croscarmellose sodium, povidone, and magnesium stearate	PVA-PEG graft copolymer
HERNEXEOS	Zongertinib	536	60 mg	Colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, mannitol, microcrystalline cellulose, and sodium stearyl fumarate	Polyvinyl alcohol
HYRNUO	Sevabertinib hydrate	485	10 mg	Microcrystalline cellulose, crospovidone, lactose monohydrate, and magnesium stearate	Hypromellose
INLURIYO	Imlunestrant tosylate	525	200 mg	Croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, and microcrystalline cellulose	Polyvinyl alcohol
JASCAYD	Nerandomilast	449	9, 18 mg	Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mannitol, and microcrystalline cellulose	Hypromellose
JOURNAVX	Suzetrigine	473	50 mg	Croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, and microcrystalline cellulose	Polyvinyl alcohol
MYQORZO	Aficamten	337	5, 10, 15, 20 mg	Croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, and sodium lauryl sulfate	Polyvinyl alcohol and PVA-PEG graft copolymer
PALSONIFY	Paltusotine HCl	456	20, 30 mg	Colloidal silicon dioxide, copovidone, crospovidone, magnesium stearate, mannitol, and microcrystalline cellulose	Hypromellose
RHAPSIDO	Remibrutinib	507	25 mg	Copovidone, croscarmellose sodium, mannitol, microcrystalline cellulose, sodium lauryl sulfate, and sodium stearyl fumarate	Polyvinyl alcohol
VANRAFIA	Atrasentan HCl	511	0.75 mg	Crospovidone, glyceryl dibehenate, lactose monohydrate, L-cysteine hydrochloride monohydrate, and silicon dioxide.	Hypromellose
WAYRILZ	Rilzabrutinib	666	400 mg	Crospovidone, microcrystalline cellulose, and sodium stearyl fumarate	Polyvinyl alcohol
ZEGFROVY	Sunvozertinib	584	150, 200 mg	Colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose	Hypromellose

Table 2. Details of hard capsule formulations

Proprietary name	Active ingredient(s)	Mol wt (free acid / base)	Strength(s)	Excipients (fill)	Capsule material
GOMEKLI	Mirdametinib	482	1, 2 mg	Croscarmellose sodium, magnesium stearate, and microcrystalline cellulose	Gelatin
IBTROZI	Taletrectinib adipate	406	200 mg	Colloidal silicon dioxide, low-substituted hydroxypropyl cellulose, mannitol, pregelatinized starch, and sodium stearyl fumarate	Hypromellose
KOMZIFTI	Ziftomenib	718	200 mg	Croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and sodium lauryl sulfate	Hypromellose
MODEYSO*	Dordaviprone di-HCl	386	125 mg	Magnesium stearate, microcrystalline cellulose, and sodium starch glycolate	Hypromellose
NEREUS	Tradipitant	588	85 mg	Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate	Gelatin
ROMVIMZA	Vimseltinib dihydrate	432	14, 20, 30 mg	Crospovidone, lactose monohydrate, and magnesium stearate	Gelatin

*Capsule contents can be emptied and dispersed in liquid if required

Table 3. Details of softgel formulation

Proprietary name	Active ingredient	Mol wt (free acid / base)	Strength(s)	Excipients (fill)
LYNKUET	Elinzanetant	669	60 mg	All-rac-α-Tocopherol, caprylocaproyl macrogolglycerides, glycerol monocaprylocaprate, glycerol mono-oleate, and polysorbate 80

Table 4. Products for oral solution or suspension

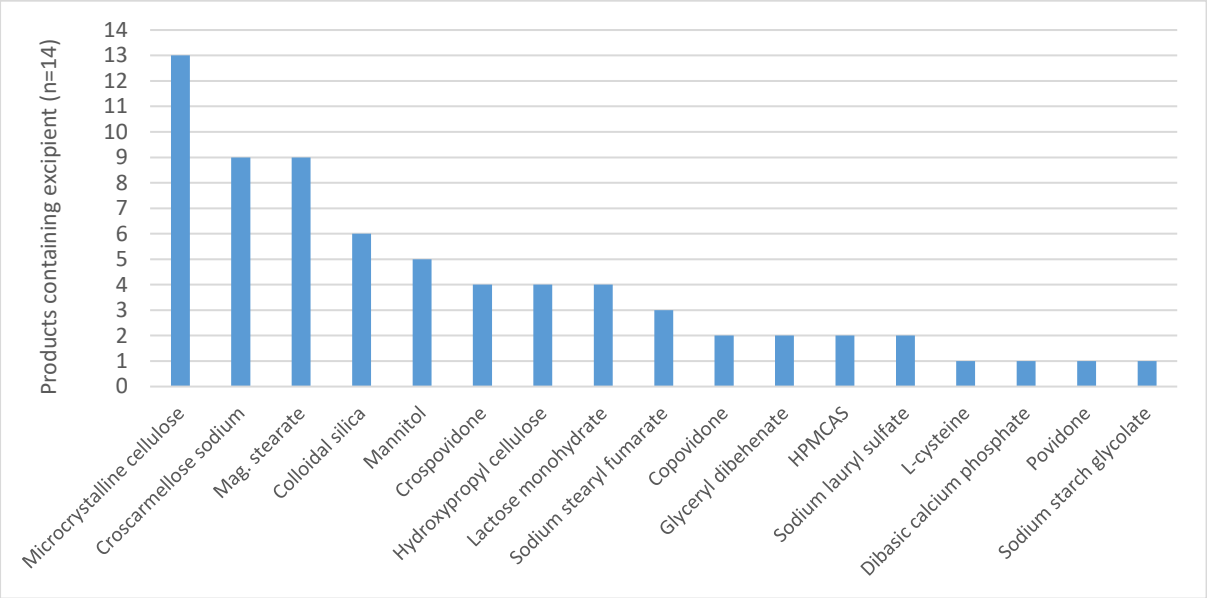
Proprietary name	Dose form	Active ingredient(s)	Mol wt (free acid / base)	Strength(s)	Excipients
GOMEKLI	Tablet for oral suspension	Mirdametinib	482	1 mg	Croscarmellose sodium, magnesium stearate, microcrystalline cellulose, grape flavour, and sucralose
KYGEVVI	Powder for oral solution	Doxecitine	227	2000 mg	Colloidal silicon dioxide and magnesium stearate
		Doxribtimine	242	2000 mg	
NUZOLVENCE	Powder for oral suspension	Zoliflodacin	487	3000 mg	Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, talc, and xanthan gum
SEPHIENCE	Oral powder	Sepiapterin	237	250, 1000 mg	Colloidal silicon dioxide, croscarmellose sodium, isomalt, magnesium stearate, mannitol, microcrystalline cellulose, sucralose, and xanthan gum

Excipients

- ***Film-coated tablets***

Excipients used in the tablet core are displayed in Figure 1. While no manufacturing details are provided within the Prescribing Information, certain information can be inferred from the excipients used. For example, two formulations (JOURNAVX and HERNEXEOS) contain hydroxypropyl methylcellulose acetate succinate (HPMCAS), and two (PALSONIFY and RHAPSIDO) contain copovidone: these formulations likely contain drug in the form of an amorphous solid dispersion (ASD). Note: PALSONIFY patent literature describes copovidone-based ASDs.

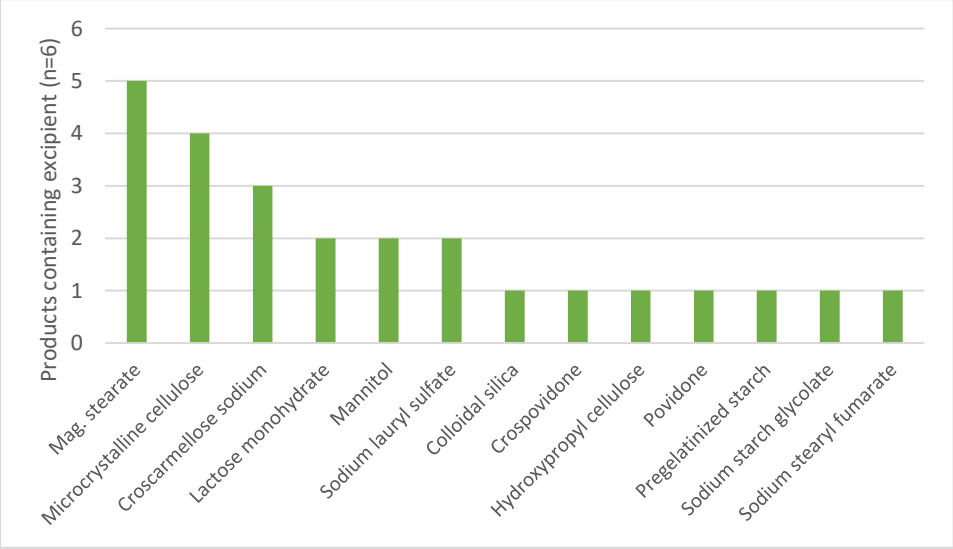
Figure 1. Excipients used in tablet formulations (core)



- ***Hard capsules***

Three of the six products use hypromellose capsule shells and the remainder use gelatin shells (Table 2). Excipients appearing in the capsule fill formulations are displayed in Figure 2. The excipients in each product are indicative of formulations manufactured using granulation and/or blending processes.

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).

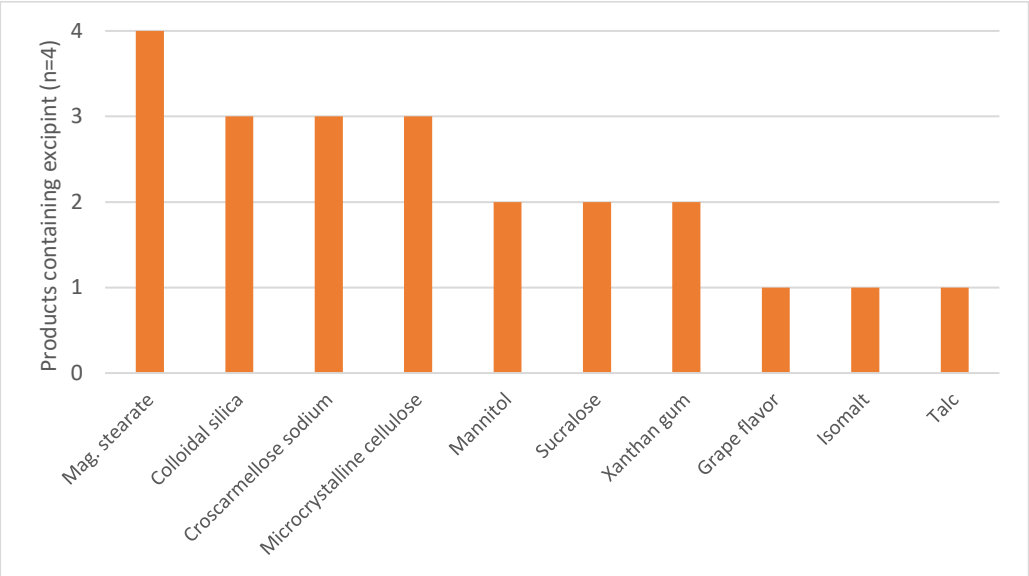
- ***Products for oral solution or suspension***

This set of products comprises one dispersible tablet (low dose) and three powders (high dose). The dispersible tablet (GOMEKLI) was also approved as a hard capsule (Table 2). Excipients appearing in the four products are displayed in Figure 3.

SEPHIENCE is described an oral powder and is intended to be mixed with water, apple juice or soft foods prior to administration.

KYGEVVI and NUZOLVENCE contain no sweeteners or flavours, and dose preparation is restricted to water, which would suggest that the taste of the drug compounds within these products is well tolerated.

Figure 3. Excipients used in products for oral solution or suspension



Summary

Twenty-four novel oral small molecules were approved by the FDA in 2025. Based on the information available within the reviewed documentation, most of the products appear to utilize “conventional” formulation technologies. Based on their excipients, four film-coated tablets probably contain drug in the form of an amorphous solid dispersion. One softgel product is a self-emulsifying drug delivery system.