

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

Introduction

This document provides an overview, from a pharmaceuticals point of view, of novel small molecule drugs (NCEs) approved by the European Medicines Agency in 2025 as oral dosage forms. The sole data source is the Public Assessment Report for the respective products.

Nineteen novel oral small molecule drug products were approved during 2025 and collectively contained 21 active ingredients. There are 20 different formulations: one product contains three active ingredients, and one product was approved as two formulations (hard capsule and dispersible tablet).

Product overview

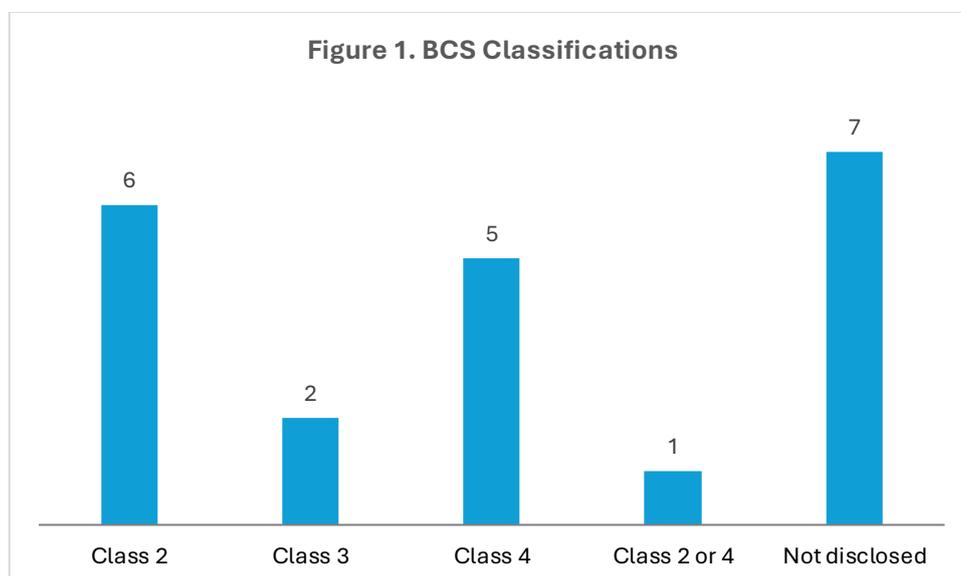
Product details are summarized in Table 1 (twelve immediate-release film-coated tablets), Table 2 (three immediate-release hard capsules) and Table 3 (five miscellaneous dosage forms).

Drug substance

Six of the 21 active ingredients are in the form of salts comprising calcium, dihydrobromide, hydrochloride, mesylate, sodium and tosylate. There is one co-crystal (vorasidenib hemicitric acid hemihydrate).

The average drug molecular weight (free acid/base) is 490 g/mol (range 237 - 968 g/mol).

The BCS Classification is disclosed for 14 of the 21 active ingredients; the compounds are predominantly in either Class 2 or Class 4 (Figure 1).



Dose strength

Excluding the suspension product (DUVYZAT) there are 39 different dose units across the remaining 18 products, with an average strength of 107 mg (range 1 - 1000 mg).

Table 1. Details of film-coated tablet formulations

Proprietary name	Active(s)	MW (free acid/base)	BCS Class	Dose strength(s)	Excipients (tablet core)	Coating	Manufacture
ALYFTREK	Deutivacaftor	402	2 or 4	50 mg 125 mg	Croscarmellose sodium, hypromellose, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate	Hypromellose	Dry granulation: DEUT and TEZ are prepared as separate SDDs. VANZ incorporated as crystalline DS.
	Tezacaftor	520	2	20 mg 50 mg			
	Vanzafactor calcium dihydrate	618	2	4 mg 10 mg			
AUMSEQA	Aumolertinib mesylate	526	Not disclosed	55 mg	Microcrystalline cellulose, sodium starch glycolate, lactose, sodium stearyl fumarate, magnesium stearate	Polyvinyl alcohol	"Standard process"
BRINSUPRI	Brensocatic	420	Not disclosed	25 mg	Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycolate, colloidal silica; glycerol dibehenate	Polyvinyl alcohol	"Standard process"
EKTERLY	Sebetralstat	492	4	300 mg	Microcrystalline cellulose, croscarmellose sodium, povidone K30, magnesium stearate	Macrogol PVA grafted copolymer	Dry granulation
INLURIYO	Imlunestrant tosylate	524	Not disclosed	200 mg	Croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose	Polyvinyl alcohol	"Standard process"
ITOVEBI	Inavolisib	407	3	3, 9 mg	Lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate	Polyvinyl alcohol	Dry granulation
MYQORZO	Aficamten	337	Not disclosed	5, 10, 15, 20 mg	Croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, sodium lauryl sulfate	Macrogol PVA grafted copolymer	Wet granulation
OGSIVEO	Nirogacestat dihydrobromide	490	4	50, 100, 150 mg	Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate	Macrogol PVA grafted copolymer	Dry granulation
REZDIFFRA	Resmetirom	435	4	60, 80, 100 mg	Microcrystalline cellulose, mannitol, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate	Polyvinyl alcohol	Direct compression
VORANIGO	Vorasidenib hemicitric acid hemihydrate	415	2	10, 40 mg	Microcrystalline cellulose, croscarmellose sodium, silicified microcrystalline cellulose, magnesium stearate, sodium lauryl sulfate	Hypromellose	Direct compression
WAYRILZ	Rilzabrutinib	666	Not disclosed	400 mg	Microcrystalline cellulose, crospovidone, sodium stearyl fumarate	Polyvinyl alcohol	Dry granulation
YEYTUO	Lenacapavir sodium	968	4	300 mg	Mannitol, microcrystalline cellulose, croscarmellose sodium, copovidone, magnesium stearate, poloxamer 407	Polyvinyl alcohol	API is prepared as SDD; incorporated into tablets by dry granulation

Table 2. Details of hard capsule (immediate release) formulations

Proprietary name	Active(s)	MW (free acid/base)	BCS Class	Dose strength(s)	Excipients (capsule fill)	Capsule material	Manufacture
EZMEKLY	Mirdametinib	482	3	1, 2 mg	Microcrystalline cellulose, croscarmellose sodium, magnesium stearate	Gelatin	Fill prepared by dry granulation
ROMVIMZA	Vimseltinib	431	2	14, 20, 30 mg	Lactose monohydrate, crospovidone, magnesium stearate	Gelatin	Fill prepared by blending process
ZURZUVAE	Zuranolone	410	2	20, 25, 30 mg	Croscarmellose sodium, mannitol, microcrystalline cellulose, colloidal silica, sodium stearyl fumarate	Gelatin	Fill prepared by blending process

Table 3. Details of miscellaneous dosage forms

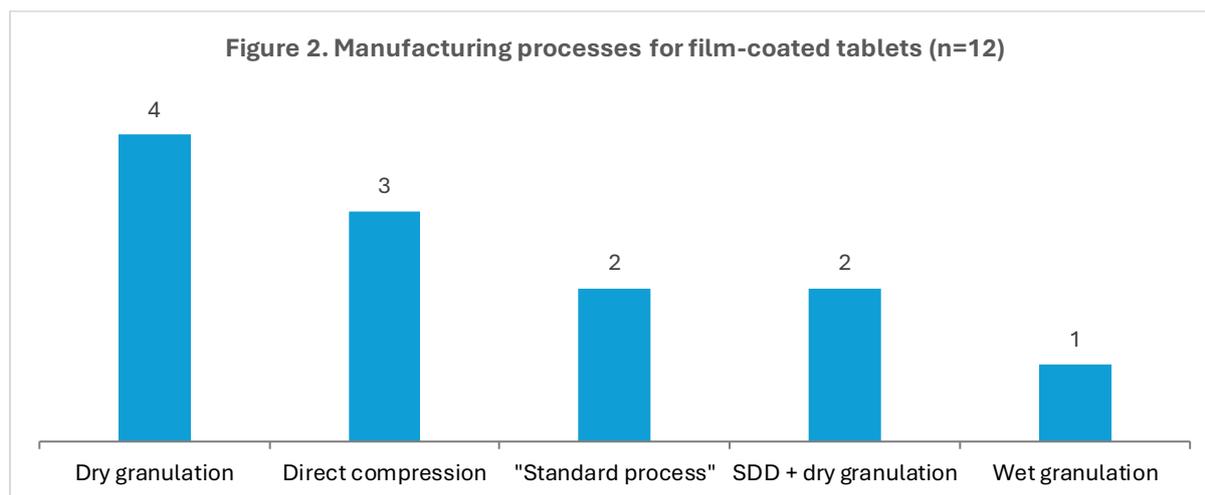
Dosage form	Proprietary name	Active(s)	MW (free acid/base)	BCS Class	Dose strength(s)	Excipients	Manufacture
Oral suspension	DUVYZAT	Givinostat HCl monohydrate	421	Not disclosed	8.86 mg/mL	Polysorbate 20, glycerol, tragacanth gum, sodium benzoate, peach flavour, cream flavour, saccharin sodium, liquid sorbitol, tartaric acid, sodium hydroxide, purified water	“Standard process”
Dispersible tablet	EZMEKLY	Mirdametinib	482	3	1 mg	Microcrystalline cellulose, croscarmellose sodium, sucralose, magnesium stearate, grape flavour	Dry granulation
Oral powder	SEPHIENCE	Sepiapterin	237	4	250, 1000 mg	Microcrystalline cellulose, isomalt, mannitol, croscarmellose sodium, xanthan gum, colloidal silicon dioxide, sucralose, magnesium stearate	Dry granulation
Softgel	LYNKUET	Elinzanetant	669	2	60 mg	All-rac- α -tocopherol, caprylocaproyl macroglycerides, glycerol monocaprylocaprate, glycerol mono-oleate, polysorbate 80	Melting, mixing, preparation of shell mass, encapsulation, drying and packaging
Gastro-resistant hard capsule	RIULVY	Tegomil fumarate	418	Not disclosed	174, 348 mg	Capsule fill comprises Enteric-coated Minitablets: Microcrystalline cellulose, croscarmellose sodium, talc, colloidal anhydrous silica, magnesium stearate, hypromellose, hydroxypropylcellulose, titanium dioxide, triethyl citrate, methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30%, poly(vinylalcohol), macrogol, iron oxide, yellow	Minitablets prepared by direct compression, coated and encapsulated into hard gelatin capsules

Dosage forms

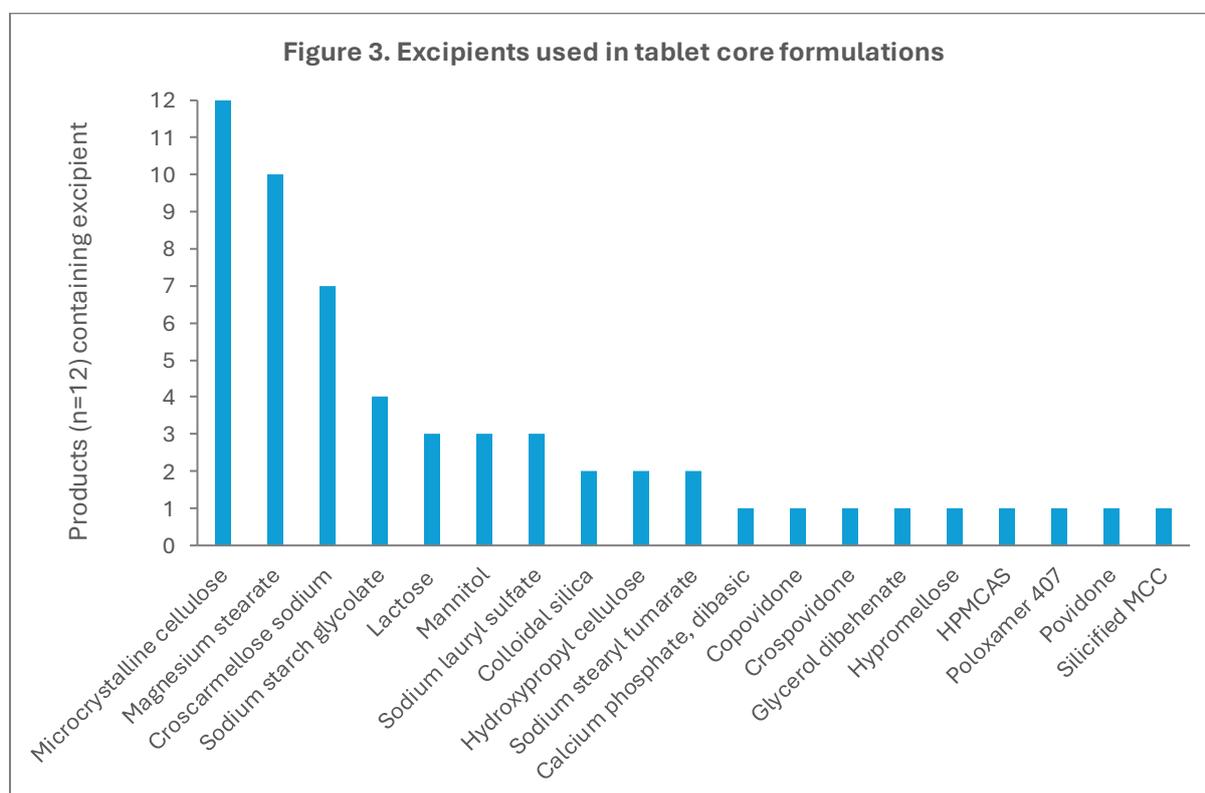
1. Film-coated tablets

Dry granulation is the predominant process disclosed for tablet preparation. For three products, no details on manufacturing process are provided other than “standard process” i.e. dry/wet granulation or direct compression) (Figure 2).

Two of the products contain drug in the form of an amorphous solid dispersion prepared by spray-drying (SDD); one of these products is ALYFTREK, where two of the three APIs are in the form of SDDs.

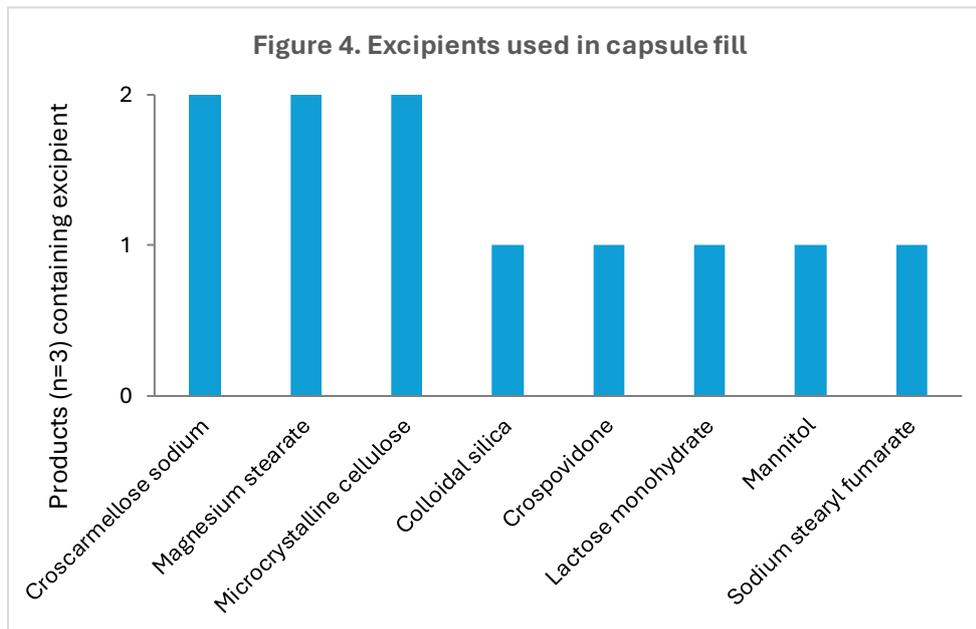


Excipients used in the tablet cores are displayed in Figure 3. Hypromellose acetate succinate (HPMCAS) is one of the excipients used in ALYFTREK, presumably as part of the SDDs. The SDD in YEYTUO is prepared using copovidone and poloxamer 407.



2. Hard capsules (immediate release)

Two of the capsule fills are prepared by blending and the other uses a dry granulation process. Excipients are displayed in Figure 4. All products use gelatin shells.



3. Miscellaneous dosage forms

Five dosage forms have been placed into a Miscellaneous category in this review. These comprise a suspension, dispersible tablet, oral powder, softgel and modified-release (gastro-resistant) capsule (Table 3).

- DUVYZAT is an oral suspension intended for use in patents aged 6 years and above.
- The dispersible tablet (EZMEKLY) was also approved as a hard capsule (Table 2)
- The oral powder (SEPHIENCE) is mixed with water, apple juice or soft foods prior to administration
- The softgel (LYNKUET) contains excipients consistent with a self-emulsifying drug delivery system
- RIULVY comprises enteric-coated mini tablets which are filled into a hard gelatin capsule

Summary

Nineteen novel oral small molecule drug products were approved by the EMA during 2025, comprising 20 different formulations collectively containing 21 active ingredients. The most common dosage form was an immediate-release film-coated tablet; two of these formulations contain amorphous drug in the form of a spray-dried dispersion.