

Kollitab™ DC 87 L: **Your new *All-in-One* Tableting Solution**

Commercial Presentation – EXTERNAL
December 2021

What are All-in-One Coprocessed Excipients?



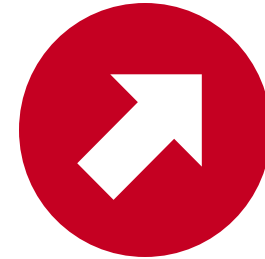
A single product with all the functionalities of the individual excipients that comprise it.

External
Internal

What are All-in-One Coprocessed Excipients?

AIMS

- Enhance functional material properties
- Optimize performance
- Overcome blending & processing challenges



RESULTS

- Cost savings
- Faster drug development
- Reduced time-to-market



Benefits of All-in-One Coprocessed Excipients

Purchasing

- ✓ Simplifies sourcing and ordering activities
- ✓ Less inventory with one ingredient
- ✓ **Accelerates supplier qualification**

Product Development

- ✓ Simplifies formulation development (e.g., consolidates Quality by Design efforts)
- ✓ Formulation predictions through ZoomLab™
- ✓ **Shortens time-to-market**

Quality & Regulatory

- ✓ Based on monographed excipients
- ✓ Advantages of all-in-one products (reduced Quality Control testing, material handling, and documentation)
- ✓ **Minimizes testing expenses**

Manufacturing

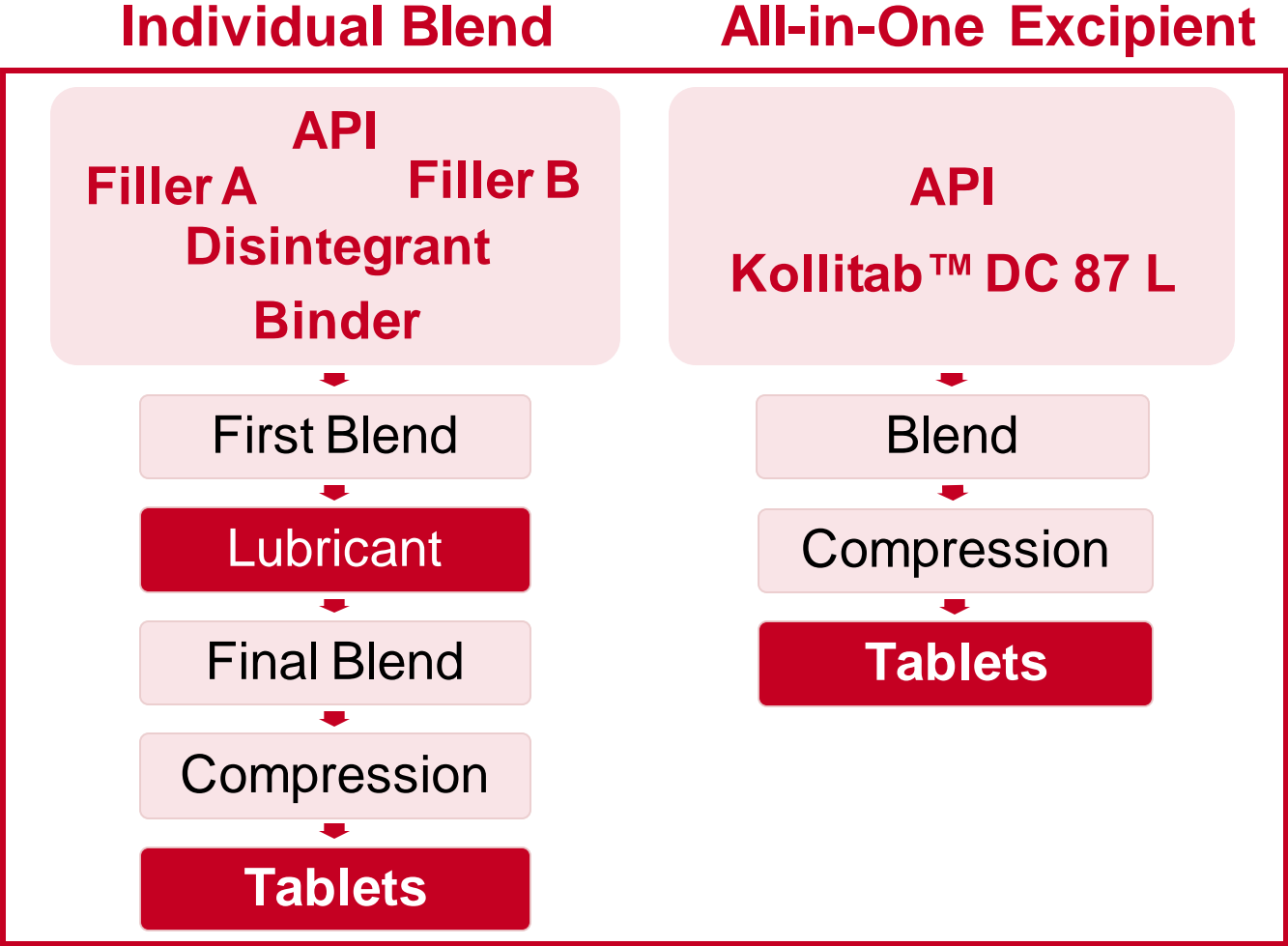
- ✓ Intended for direct compression
- ✓ Decreases complexity (fewer weighing, dispensing, and documentation steps)
- ✓ **Streamlines processing**

Simpler Formulation and Faster Process with Kollitab™ DC 87 L

More Weighing & Dispensing Steps

Increased Manufacturing Complexity

Too many excipients = Higher variability



Simple Direct Compression Formulation

Kollitab™ DC 87 L

Your new *all-in-one* tableting solution

“Kollitab™ DC 87 L”

Kollitab™	BASF's brand name for our new coprocessed excipients generation for tableting.
DC	For <u>D</u>irect <u>C</u>ompression manufacturing
87	Percent (%) of filling material
L	L= Lactose (filling material used)

Kollitab™ DC 87 L

Your new *all-in-one* tableting solution

Filler: **Lactose** (~87%)

Disintegrant: **Kollidon® CL F** (~9%)

Binder: **Kollicoat® IR** (~3%)

Lubricant: **Sodium stearyl fumarate** (~1%)



All essential functionalities for immediate release tableting –
enabling **fast and simple formulation.**

What can Kollitab™ DC 87 L do for you?



Superior flowability

- ▶ For low weight variability and high process robustness



High tablet hardness at broad compression forces

- ▶ Minimize tablet defects for coating and packaging
- ▶ Reduce machines stress and punch damage



Fast disintegration

- ▶ Minimize impact on drug dissolution

What are customers saying?



“ Kollitab™ DC 87 L absolutely meets our expectations at IMA Active. We tested it thoroughly and achieved consistent, excellent results: low weight relative standard deviation, stable thickness and enhanced tablet strength! **”**

Federica Giatti
Process Development R&D Laboratory, IMA Active

BASF
We create chemistry

#CustomerVoices

APIs Successfully Formulated with Kollitab™ DC 87 L

Successfully Formulated APIs

- ✓ **Acetylsalicylic acid***
Enteric release tablets, 81 and 325 mg
- ✓ **Acetylsalicylic acid***
Film-coated immediate release tablets, 100 mg
- ✓ **Cetirizine**
Immediate release tablets, 10 mg
- ✓ **Dimenhydrinate**
Film-coated immediate release tablets, 50 mg
- ✓ **Enalapril maleate**
Film-coated immediate release tablets, 5 to 40 mg
- ✓ **Ibuprofen***
Film-coated immediate release tablets, 200 mg
- ✓ **Loperamide***
Immediate release tablets, 2 mg
- ✓ **Paracetamol***
Film-coated immediate release tablets, 100 mg
- ✓ **Propranolol HCl***
Film-coated immediate release tablets, 40 and 80 mg
- ✓ **Valsartan**
Film-coated immediate release tablets, 80 and 160 mg
- ✓ **Vardenafil HCl**
Film-coated immediate release tablets, 10 and 20 mg

Potential Candidates from WHO List of Essential Medicine

- **Amitriptyline**
10, 25, and 75 mg
- **Atazanavir sulphate**
100 and 300 mg
- **Bedaquiline**
100 mg
- **Clofazimine**
50 and 100 mg
- **Codeine phosphate**
30 mg
- **Cyclizine**
50 mg
- **Cycloserine**
125 mg
- **Darunavir**
75 mg
- **Delamanid**
50 mg
- **Dexamethasone**
2 and 4 mg
- **Diazepam**
5 and 10 mg
- **Diethylcarbamazine**
50 and 100 mg
- **Ethambutol HCl**
100 mg
- **Ethionamide**
125 and 250 mg
- **Fluoxetine HCl**
20 mg
- **Haloperidol**
0.5, 2 and 5 mg
- **Isoniazid**
100 mg
- **Ivermectin**
3 mg
- **Lamotrigine**
25, 50, 100 and 200 mg
- **Levamisole HCl**
50 and 150 mg
- **Loratadine**
10 mg
- **Methadone HCl**
5 and 10 mg
- **Metoclopramide HCl**
10 mg
- **Midazolam**
7.5 and 15 mg
- **Morphine sulphate**
10 mg
- **Phenobarbital**
15 mg to 100 mg
- **Phenytoin (Na salt)**
25, 50 and 100 mg
- **Praziquantel**
150 mg
- **Prednisolone**
5 and 25 mg
- **Rifampicin**
150 mg
- **Rifapentine**
150 mg
- **Voriconazole**
50 and 200 mg

*Listed in 21st WHO Model List of Essential Medicines (2019)

Kollitab™ DC 87 L Commercial Overview

Appearance	White, free-flowing powder
Manufacturing Site	BASF SE, Germany
PRD Number	30765743
Sample Article	50711206 (1KG plastic bottle)
Commercial Article	50708787 (20KG fiberboard box) MOQ = 600KG Pallet
Packaging Material	Primary: 150 µm PE-bag (in-liner), Secondary: Fiberboard box (60 L)



Quality & Regulatory

- **Uses approved monographed excipients** (Ph. Eur., USP-NF, JPE)
- **US DMF in progress** (2022)
- ****Samples available****

Available in RegXcellence

- ✓ Specification
- ✓ QRPI
- ✓ GMP Statement
- ✓ Manufacturing Flowchart
- ✓ Aflatoxin Pharma
- ✓ Allergens Pharma
- ✓ BSE Pharma
- ✓ Change Notification Commitment
- ✓ Compliance Information
- ✓ Contaminants Pharma
- ✓ Dioxine Pharma
- ✓ GMO Pharma
- ✓ Gluten Pharma
- ✓ Heat treatment of pallet
- ✓ Melamine Pharma
- ✓ Microbiological Information
- ✓ Nano Pharma
- ✓ Pharmacopoeial Compliance
- ✓ Phthalate Pharma
- ✓ Proposition 65 Pharma
- ✓ REACH
- ✓ Residual Solvents Pharma
- ✓ Social & Environmental Standards
- ✓ WADA Statement

Kollitab™ DC 87 L for Direct Compression

- ✓ Superior flowability
- ✓ High tablet strength at broad compression forces
- ✓ Fast tablet disintegration



- ✓ Simplifies formulation development
- ✓ Reduces manufacturing complexity
- ✓ \$\$\$ savings in inventory & QC costs



- ✓ Leverages ZoomLab™ to accelerate formulation and time-to-market through digital formulation



Kollitab™ DC 87 L

Your new *all-in-one* tableting solution

Where can I learn more?

Formulate Faster



Your Virtual Formulation Assistant

Save time and money with **ZoomLab™**. Instantly predict your next formulation now!

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Find products easily



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Find the optimal excipient or API solution for your next formulation challenge with **MyProductWorld**.

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Questions? Reach out to:
pharma-solutions@basf.com

and visit our website at:
www.pharma.basf.com



We create chemistry

BASF's Coprocessed Portfolio

	Kollitab™ DC 87 L	Ludipress®	Ludipress® LCE	Ludiflash®	Kollidon® SR
	Immediate Release				Extended Release
Main Use	Tablets	Tablets	Lozenges, Chewables, Effervescent	ODTs	Tablets
Benefits	Lubricated all-in-one excipient for simplified direct compression.	Filler, binder and disintegrant for tablets, with flexibility to choose lubricant.	Filler and binder for reduced manufacturing steps.	Extremely fast disintegration with superior mouth feel.	Highly compressible and free-flowing matrix for direct compression.
Functionality	Filler Binder Disintegrant Lubricant	Filler Binder Disintegrant	Filler Binder	Filler Binder Disintegrant	Non-erodible matrix Pore former
Composition	Lactose monohydrate Kollicoat® IR Kollidon® CL-F Na Stearyl Fumarate	Lactose monohydrate Kollidon® 30 Kollidon® CL	Lactose monohydrate Kollidon® 30	D-Mannitol Polyvinyl acetate* Kollidon® CL-SF	Polyvinyl acetate Kollidon® 30

*from Kollicoat® SR 30D

Introduction to ZoomLab™ Characterization

Particle size

d10 Value (D10),
d50 Value (D50),
d90 Value (D90),
Distribution span (DSP)

Powder density

Bulk density (DBU),
Tapped density (DTA)

Powder flow

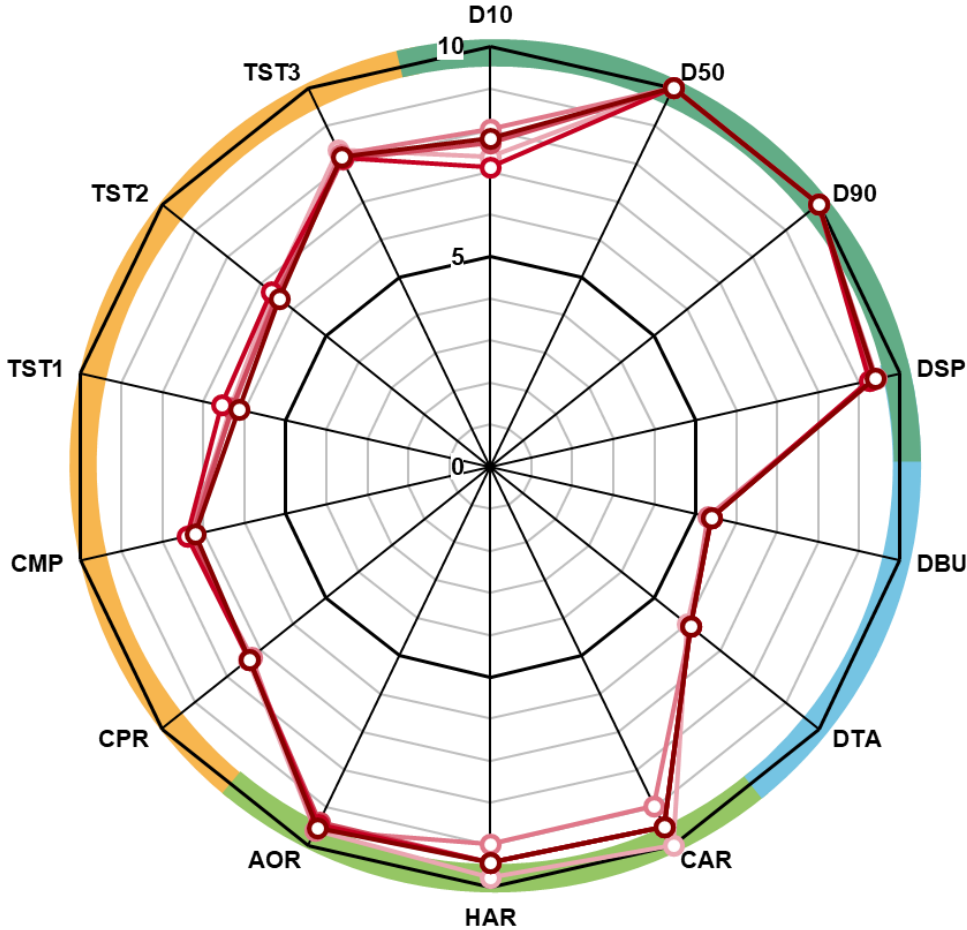
Compressibility index (CPI),
Hausner ratio (HAR),
Angle of repose (AOR)

Tabletability

Compaction pressure at 0.85 solid fraction (CPR),
Tensile strength at 0.85 solid fraction (CMP),
Tensile strength at 100 MPa pressure (TST1),
Tensile strength at 150 MPa pressure (TST2),
Tensile strength at 250 MPa pressure (TST3)

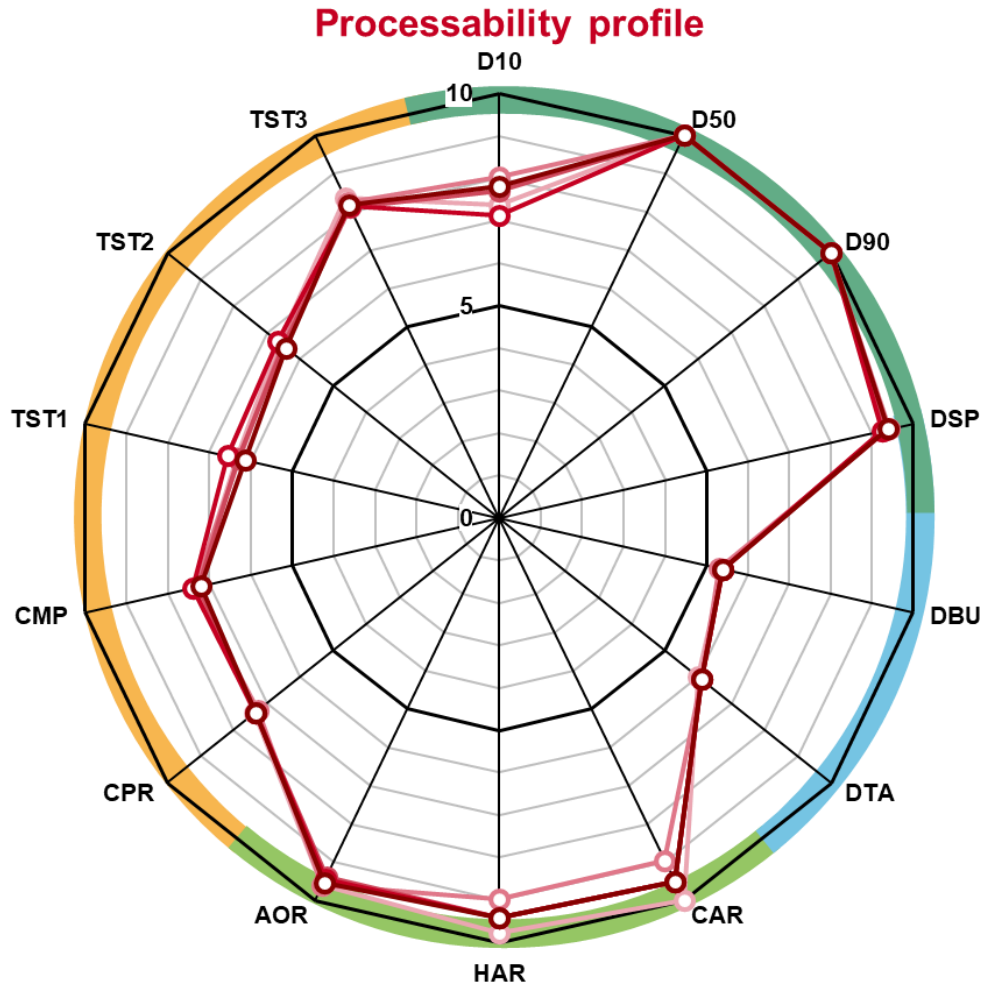


Processability profile



External
Internal

Kollitab™ DC 87 L characterized in ZoomLab™



Particle Size

Kollitab™ has narrow particle size distribution, reducing process variability.

Powder Density

Kollitab™ has a high bulk density, preventing segregation of the API + Kollitab™ blend.

Flowability

Kollitab has superior flow, reducing tablet weight variability.

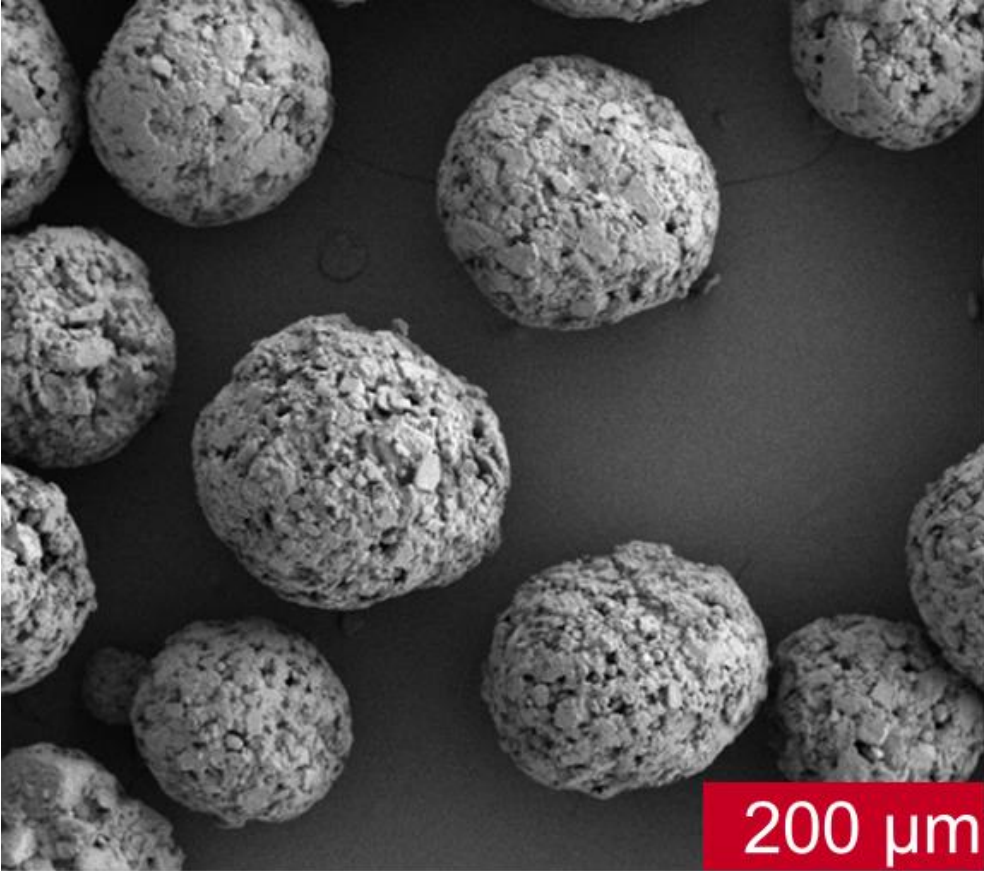
Tabletability

Kollitab™ creates high strength tablets at broad compression forces.

1. Superior Flowability for ensuring Tablet Weight Consistency

Particle Size (Malvern)

d10 (μm)	76
d50 (μm)	158
d90 (μm)	275



1. Superior Flowability for ensuring Tablet Weight Consistency

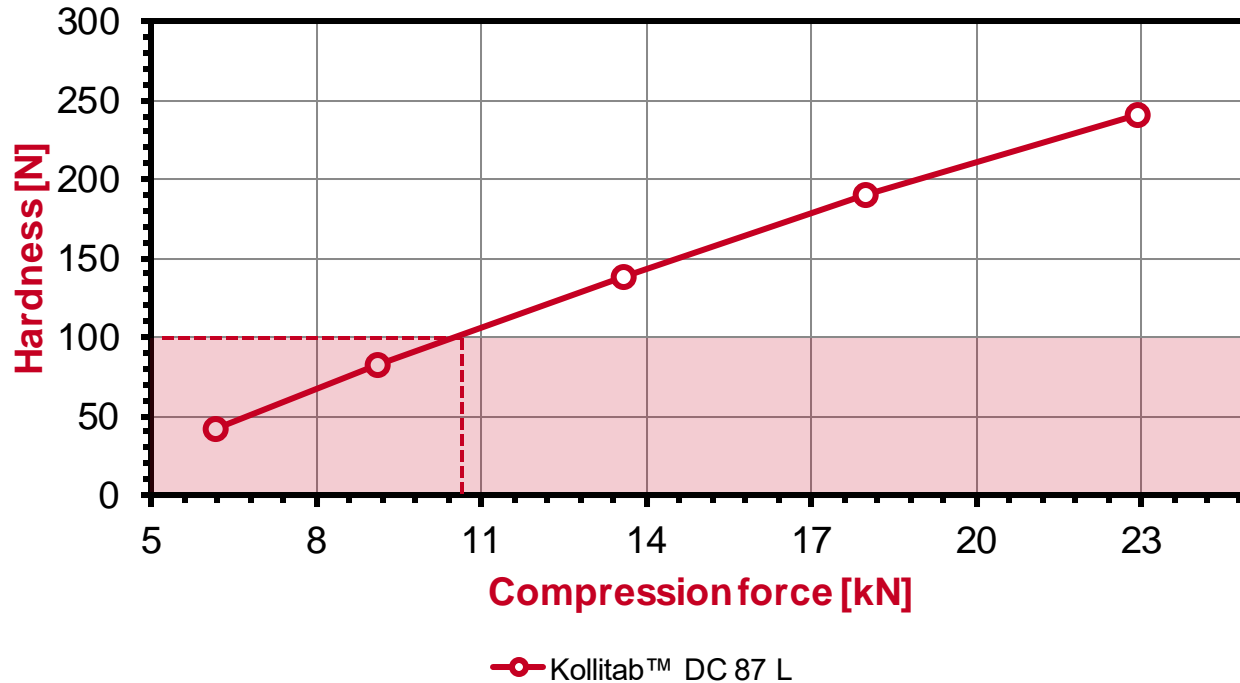
Hausner Ratio	1.09
Angle of Repose (°)	26.6
Compressibility Index (%)	8.2

Flow Character	Hausner Ratio	Angle of Repose (°)	Compressibility Index (%)
Excellent	1.00–1.11	25–30	≤10
Good	1.12–1.18	31–35	11–15
Fair	1.19–1.25	36–40	16–20
Passable	1.26–1.34	41–45	21–25
Poor	1.35–1.45	46–55	26–31
Very poor	1.46–1.59	56–65	32–37
Very, very poor	>1.60	>66	>38



2. High Tablet Hardness at Broad Compression Forces

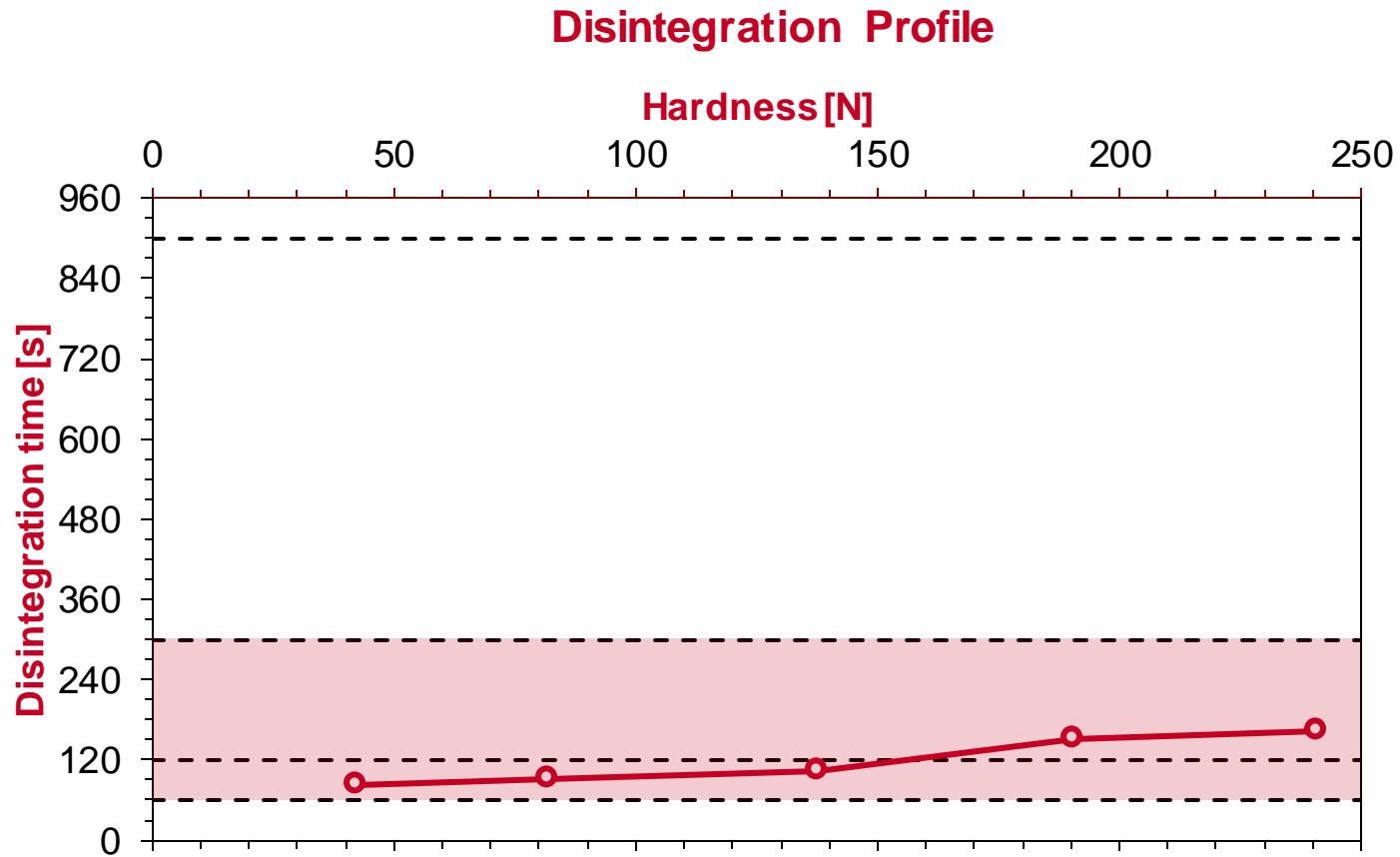
Manufacturability Profile



Kollitab™ DC 87 L: 100%
Punch: 10 mm punch
Tablet mass: 360 mg

Measurement	Target	Observation
Hardness (10 mm)	Variable	x10 of punch size
Compression Force	10 kN	Typical Low range

3. Fast Disintegration for High-Strength Tablets



Kollitab™ DC 87 L: 100%
Punch: 10 mm punch
Tablet mass: 360 mg

Case Study

Vardenafil HCl

Kollitab™ DC 87 L with Vardenafil HCl

Case Study:

- ▶ Vardenafil HCl: a weak base used for erectile dysfunction*
- ▶ Particle size: (d10): 7 µm, (d50): 28 µm, (d90): 112 µm, Span: 3.8 (high)
- ▶ **Blended for a 9mm tablet, 250mg:**
 - **2% Vardenafil HCl + 98% Kollitab™ DC 87 L**
 - **8% Vardenafil HCl + 92% Kollitab™ DC 87 L**

Challenge:

- ▶ **Formulate a cohesive API with broad particle size range for direct compression**

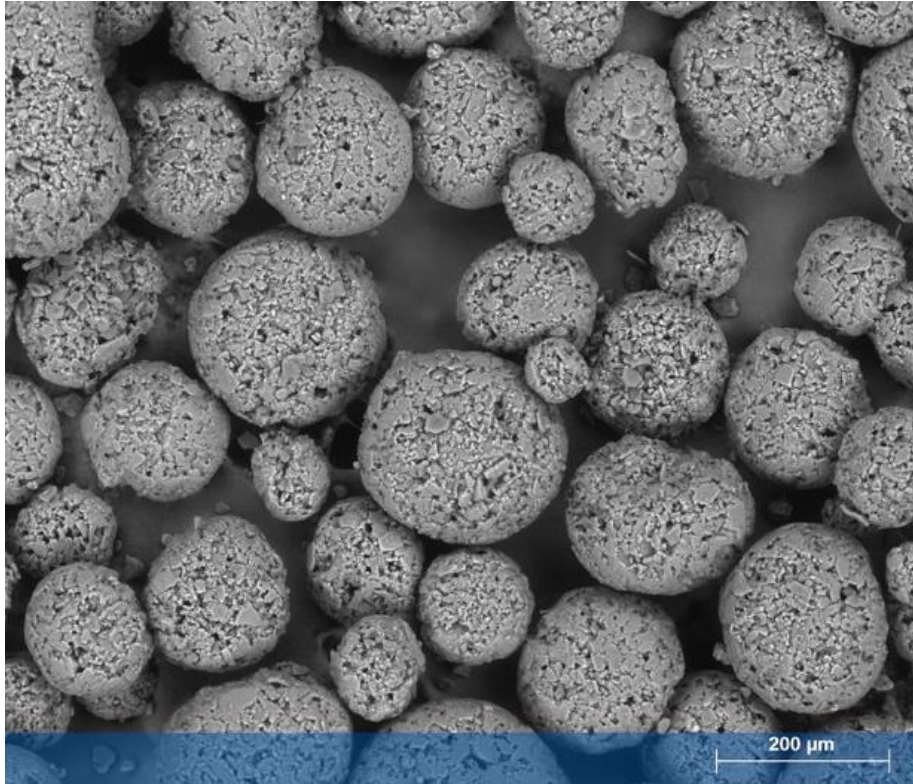
Result:

- ✓ Direct compression
- ✓ 8kN of compression force for 100N of hardness
- ✓ 3 minutes disintegration time

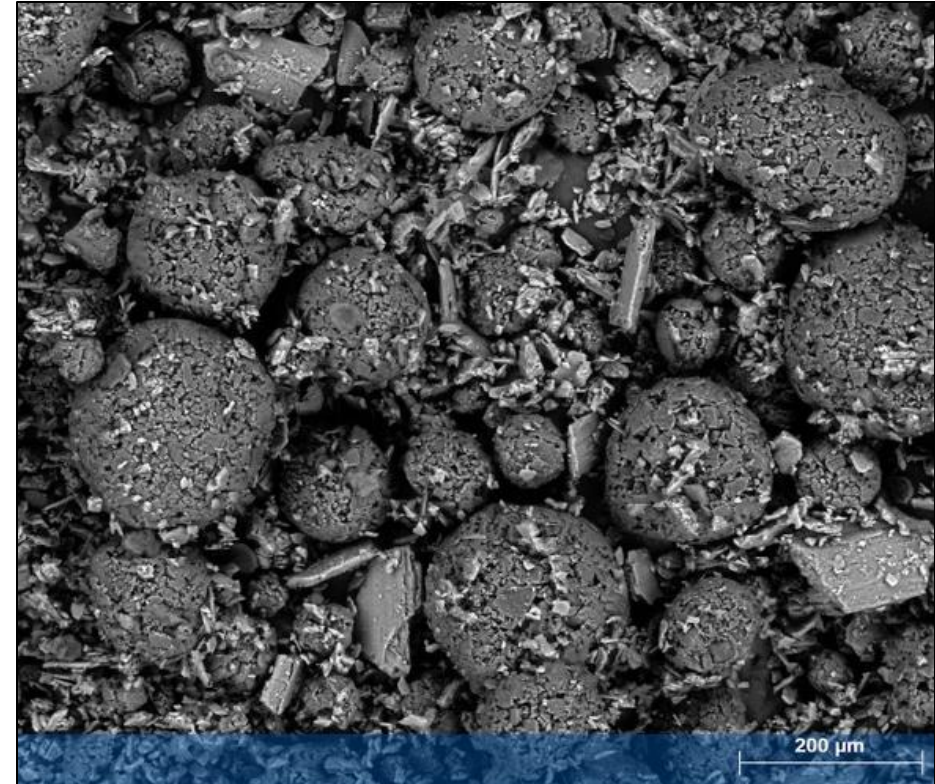
[*Levitra \(Vardenafil HCl\) Drug Information](#)

Scanning Electron Microscopy

Kollitab™ DC 87 L (100x)



Kollitab™ DC 87 L + Vardenafil HCl (100x)

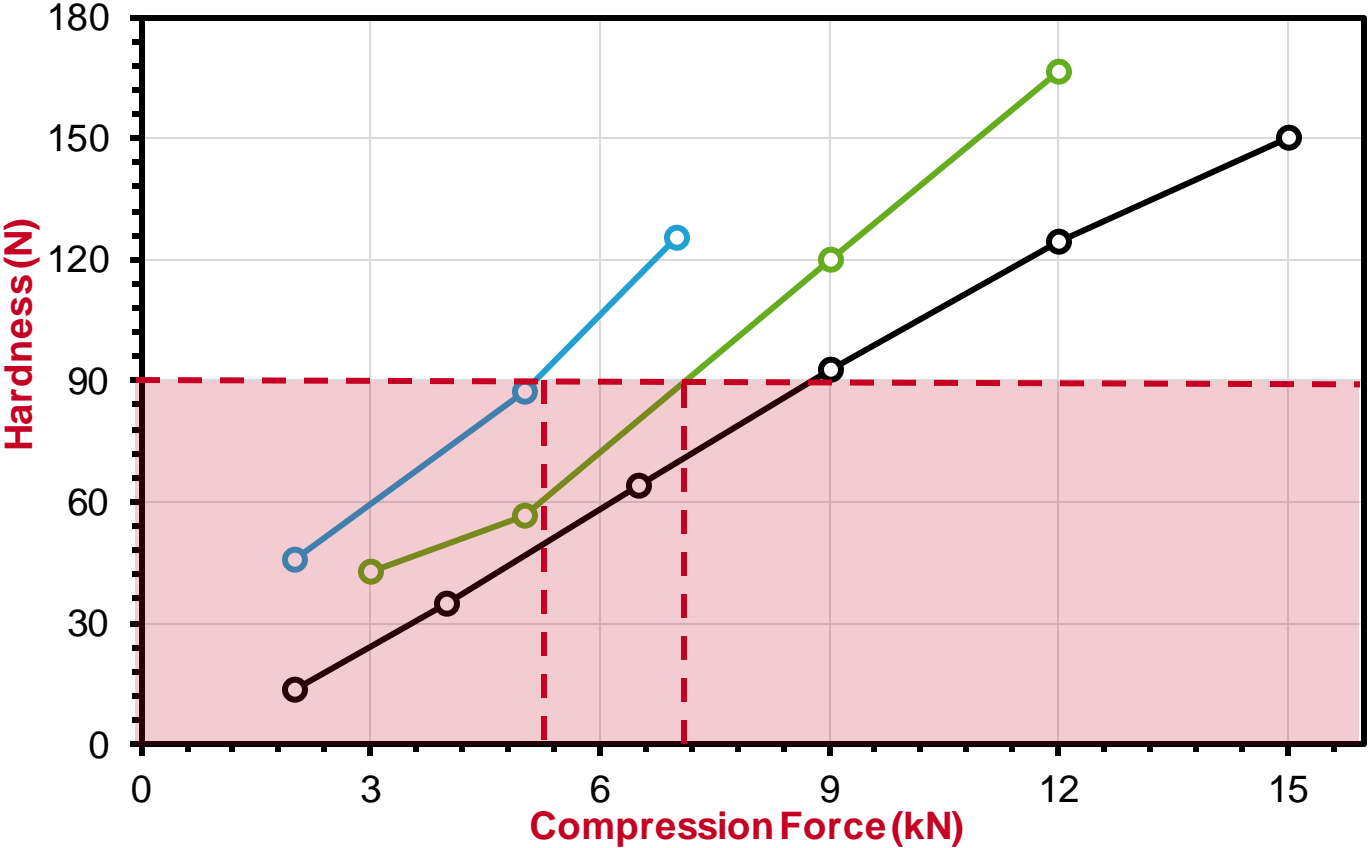


Particle size allows good blend uniformity of micronized APIs, such as Vardenafil HCl.

Kollitab™ DC 87 L with Vardenafil

Tableting Profile

Manufacturability Profile



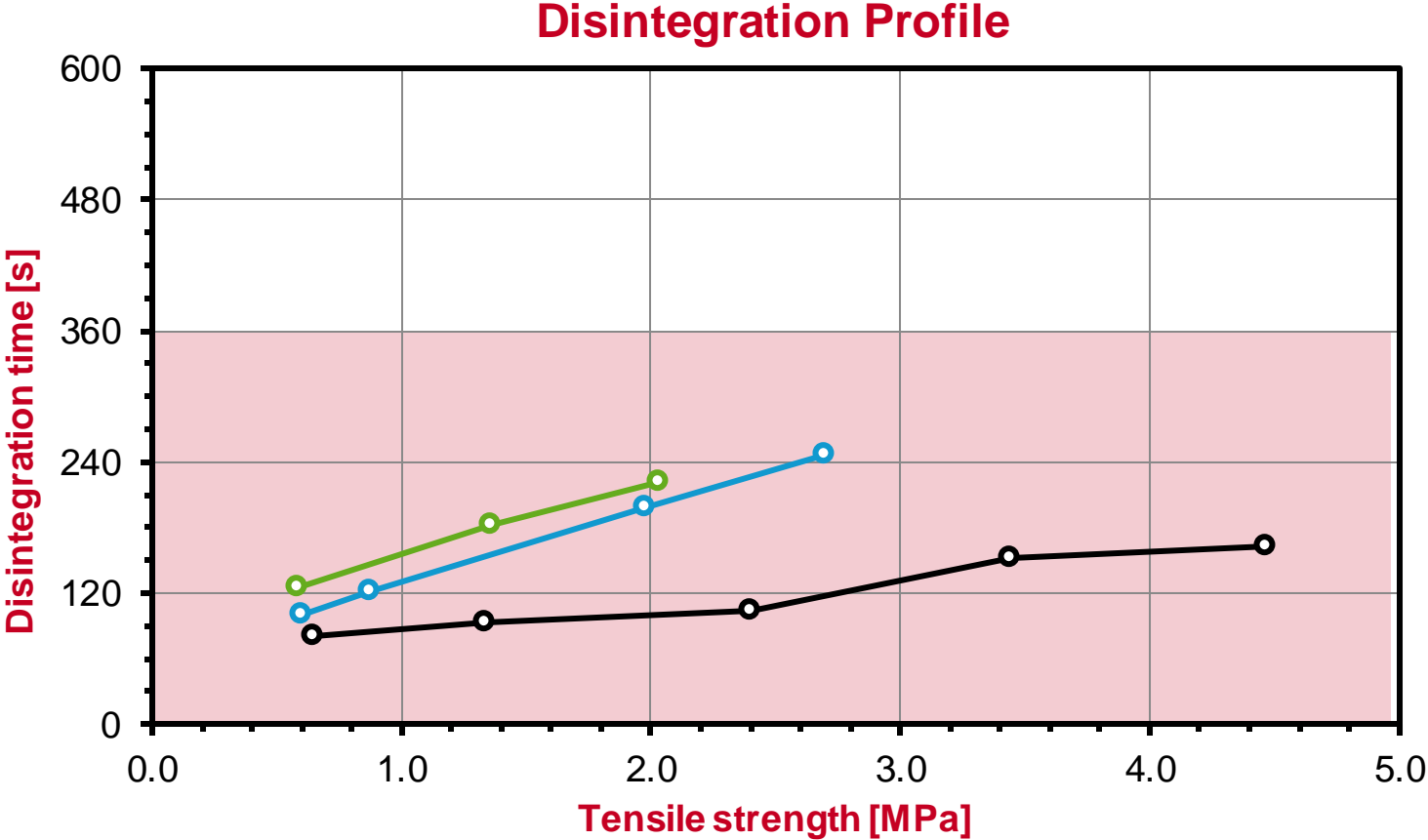
- Kollitab™ DC 87 L + 2% Vardenafil
- Pure Kollitab™ DC 87 L
- Kollitab™ DC 87 L + 8% Vardenafil

Vardenafil HCl: 2%, 8%
Kollitab™ DC 87 L: 98%, 92%
Punch: 9.0 mm
Tablet mass: 250 mg

Kollitab with Vardenafil produces **high strength tablets at low compression forces.**

Kollitab™ DC 87 L with Vardenafil

Disintegration Profile



- Kollitab DC 87 L (DT vs TS)
- Kollitab DC 87 L + 2% Vardenafil (DT vs TS)
- Kollitab DC 87 L + 8% Vardenafil (DT vs TS)

Vardenafil HCl: 2%, 8%
Kollitab™ DC 87 L: 98%, 92%
Punch: 9.0 mm
Tablet mass: 250 mg

Kollitab with Vardenafil achieves **low disintegration times even at high hardness.**

Kollitab™ DC 87 L with Vardenafil HCl

Summary

- Particle size allows good blend uniformity of micronized APIs like Vardenafil HCl.
- Kollitab™ DC 87 L with Vardenafil produces high strength tablets at low compression forces, and increasingly higher drug loads of Vardenafil require lower compression forces.
- Kollitab™ DC 87 L with Vardenafil achieves low disintegration times even at high hardness.

Case Study

Valsartan

Kollitab™ DC 87 L with Valsartan

Case Study:

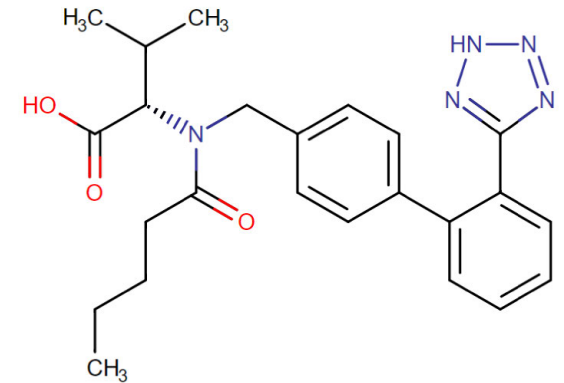
- ▶ Valsartan is an angiotensin II receptor blocker used to treat high blood pressure*
- ▶ Particle size: (d10): 59 µm, (d50): 118 µm, (d90): 217 µm, Span: 1.3
- ▶ **Blended 20% Valsartan + 80% Kollitab™ DC 87 L (7mm tablet, 200mg)**

Challenge:

- ▶ Direct compression formulation containing 20% drug load. API with medium particle size range.

Result:

- ✓ Direct compression
- ✓ 10,5 kN of compression force for 70N of hardness
- ✓ Low friability (0,06%)
- ✓ Less than 2 minutes disintegration time



*Diovan® (Valsartan) - Drug Information

Internal

Kollitab™ DC 87 L with Valsartan

Bulk Density (mg/mL)	0.5418
Tapped Density (mg/mL)	0.6478
Hausner Ratio	1.18

Valsartan: 20%
Kollitab™ DC 87 L: 80%

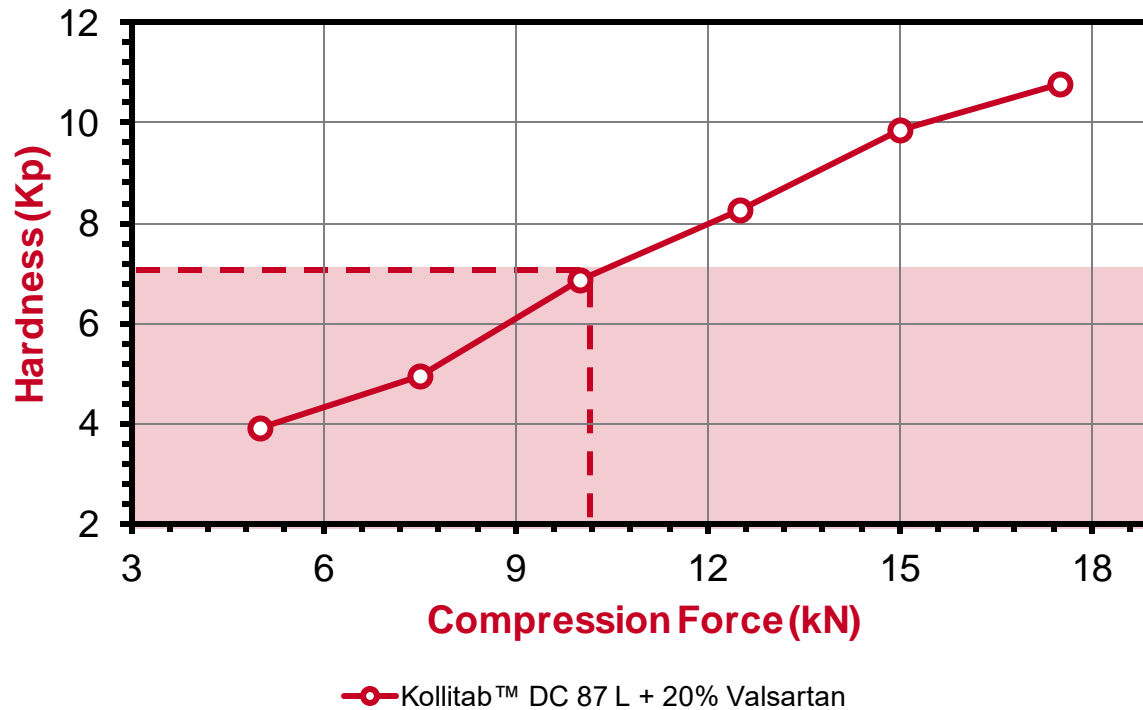
Punch: 7.0 mm
Tablet mass: 200 mg
API Dosage: 40 mg

Flow Character	Hausner Ratio
Excellent	1.00–1.11
Good	1.12–1.18
Fair	1.19–1.25
Passable	1.26–1.34
Poor	1.35–1.45
Very poor	1.46–1.59
Very, very poor	>1.60

► **Good flowability**

Kollitab™ DC 87 L with Valsartan Tableting Profile

Manufacturability Profile



Valsartan: 20%

Kollitab™ DC 87 L: 80%

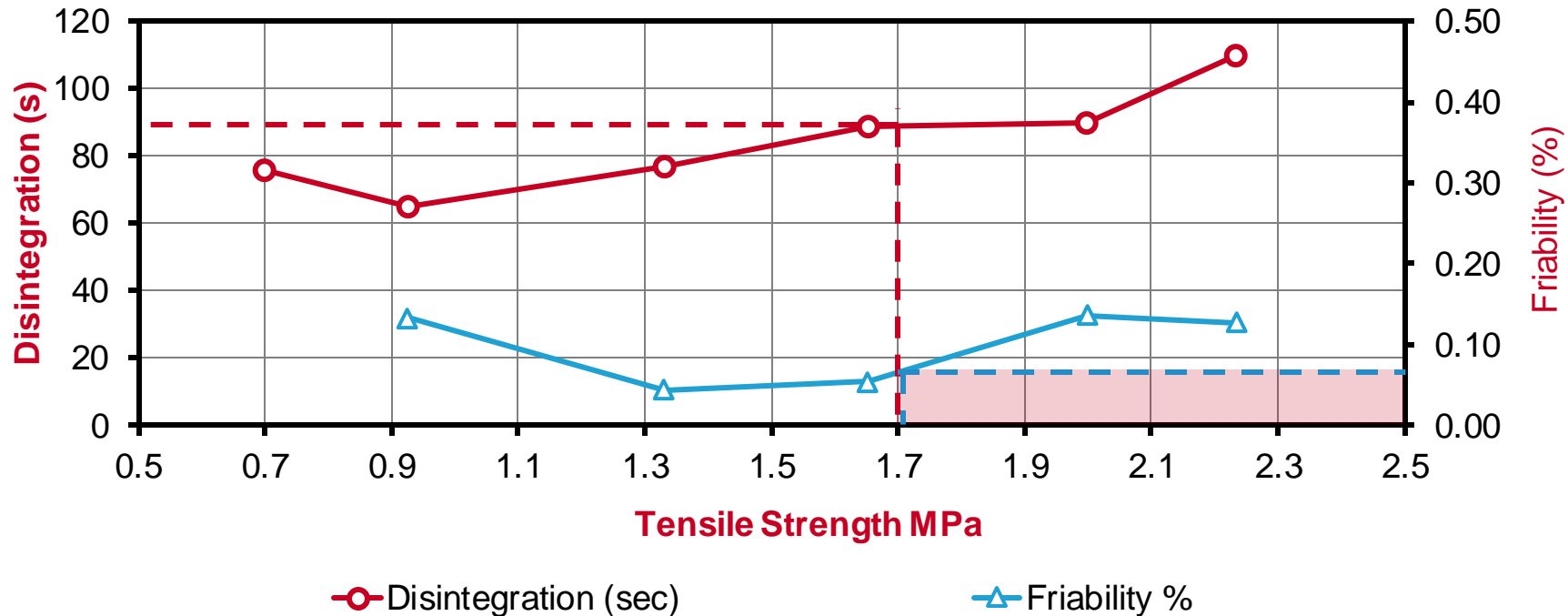
Punch: 7.0 mm

Tablet mass: 200 mg

► The hardness of 70 N was achieved with a compression force of ~10,5 kN

Kollitab™ DC 87 L with Valsartan

Disintegration and Friability x Tensile Strength



Valsartan: 20%
Kollitab™ DC 87 L: 80%
Punch: 7.0 mm
Tablet mass: 200 mg

▶ Disintegration under 100 seconds, and friability at 0.06%.

Kollitab™ DC 87 L with Valsartan

Summary

- Kollitab DC 87 L enabled a successful direct compression formulation with Valsartan at 40 mg;
- Good flowability and compressibility was observed throughout the process;
- High tensile strengths were achieved at low compression pressures;
- Even at high tensile strengths, disintegration time remained under 2 minutes.