



**galenIQ™** Isomalt (Ph. Eur., USP-NF, BP, JP)  
a brand of beneo

Great choice. Great taste.

## The functional filler-binder that makes medicine taste better

Basel, November 25th, 2016

**Dr. Michael Black**

Head of Sales Pharma

**Why is galenIQ™ the solution for you?**



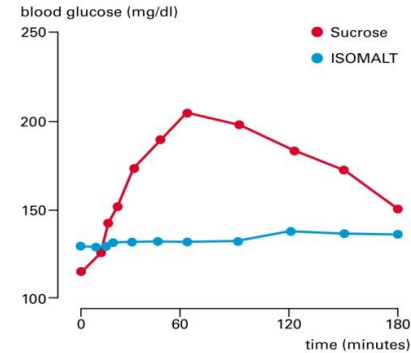
**TASTE**  
**STABILITY**  
**WORKABILITY**  
**HIGH DRUG LOAD**  
**COMPRESSIBILITY**  
**CONTENT UNIFORMITY**

# Properties of galenIQ™

- toothfriendly“
- Calorie reduced (vs. Sucrose)
- Very low glycemic response(low GI), low insulinemic, suitable for diabetics
- Supports gut health



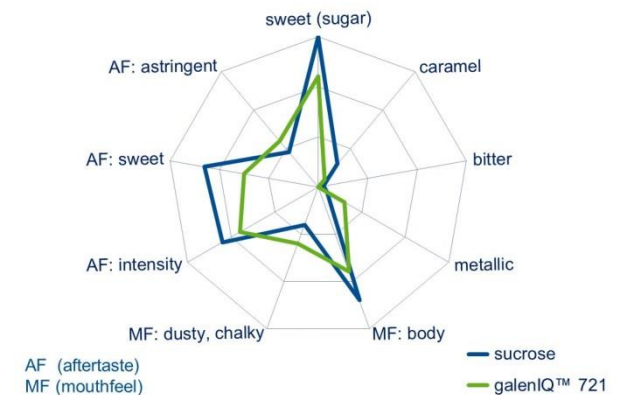
suitable for diabetics



- Chemically very resistant, e.g. against acidic or enzymatic hydrolysis
  - No Maillard Reaction or interactions with active ingredients
  - Available in different solubilities
  - Very low hygroscopic , very stable in amorphous state
- ⇒ excellent shelf life of finished products!

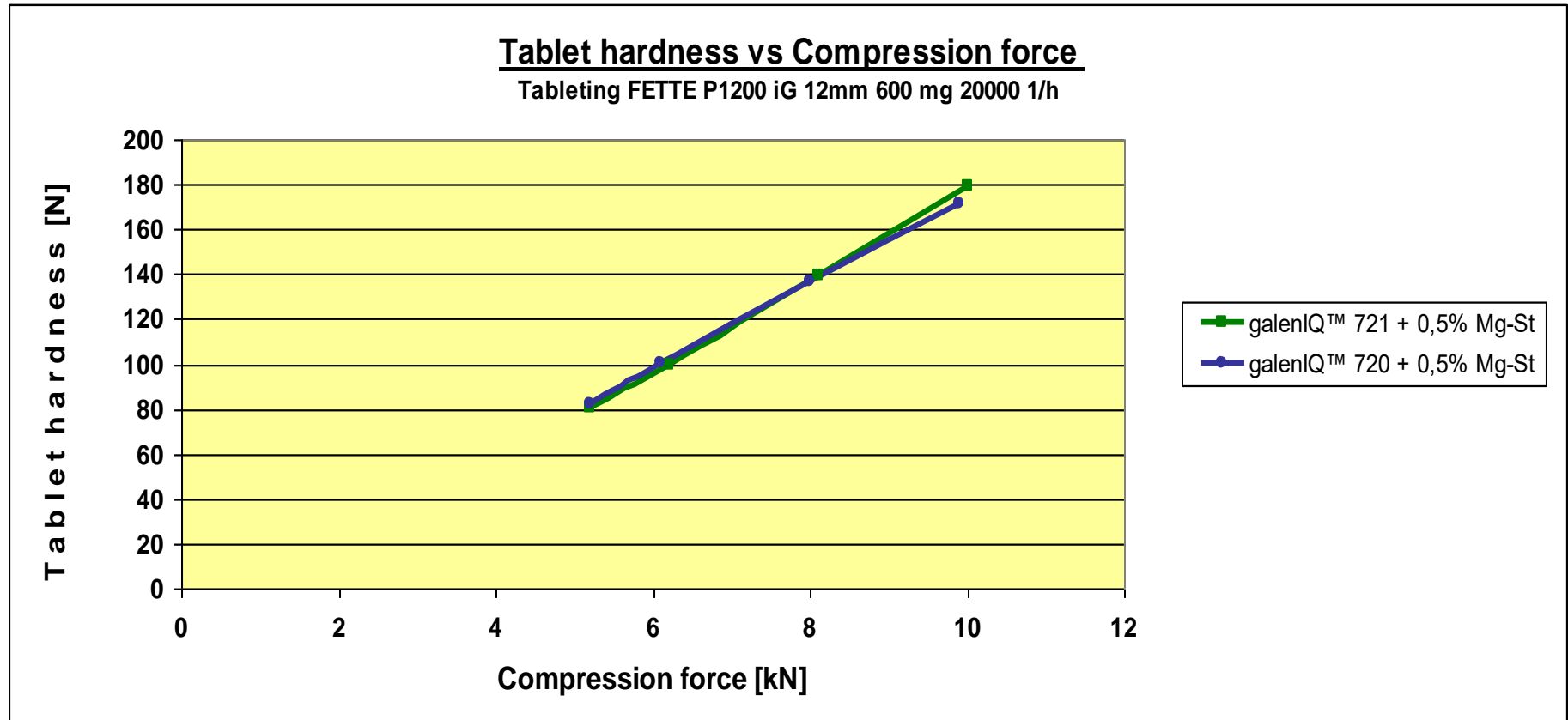
# galenIQ™ in tablet formulations

- **Flowability:** low fines content enhances flow properties of final blend
- **Mixability:** high content uniformity in low and high dosage DC formulations
- **Compressibility:** hard tablets with low compression forces
- **Good dissolution profiles**
- **Excellent stability** even with moisture sensitive drugs
- **Excellent taste** – sweet sugarlike profile and capacity for bitterness reduction



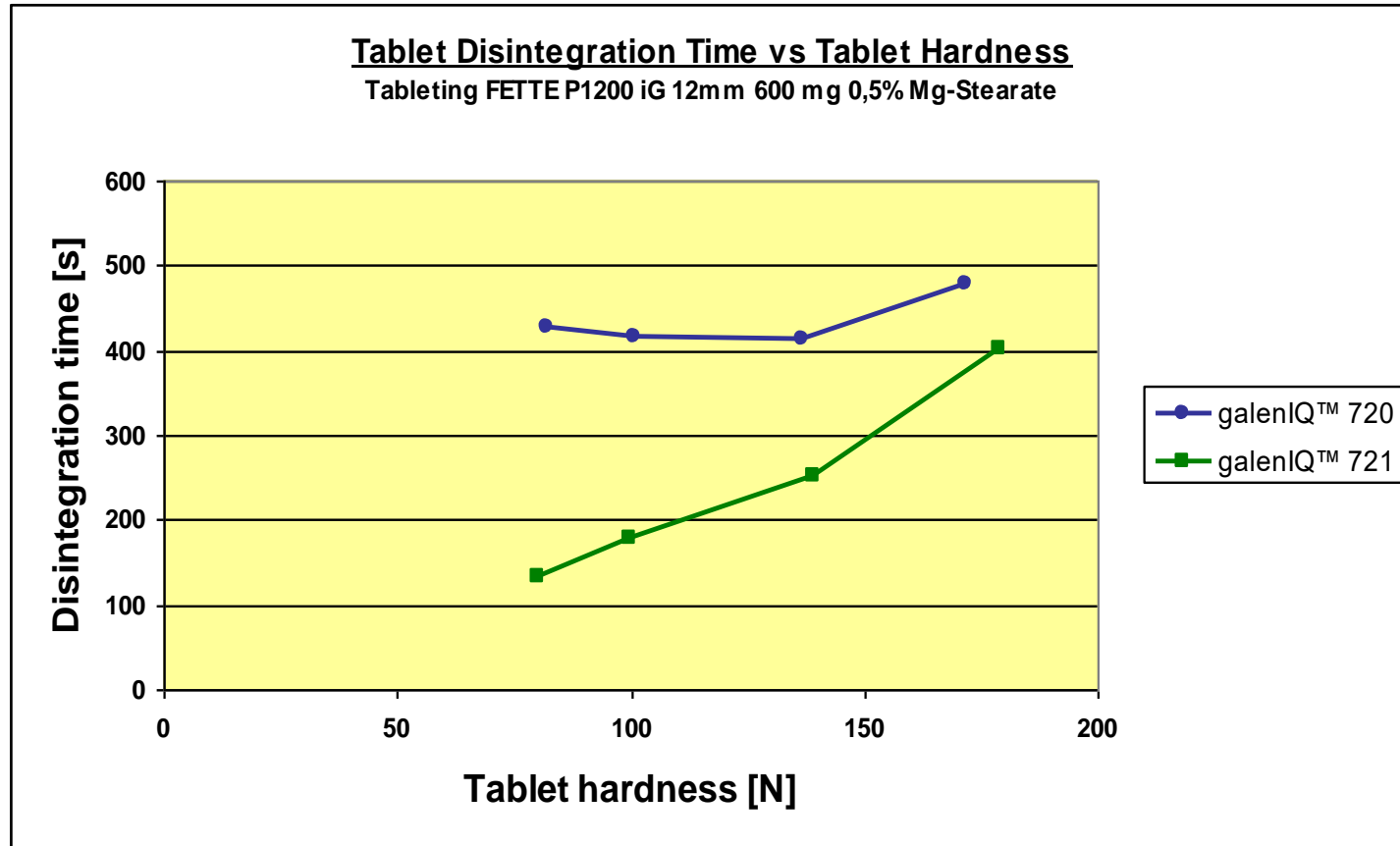
**galenIQ™ is a filler/binder for all kind of tablets!**

# galenIQ™ 720 and 721 Tablet Hardness-Compression Force Profile



Outstanding compactibility at extremely  
low compression forces

# Tablet disintegration properties

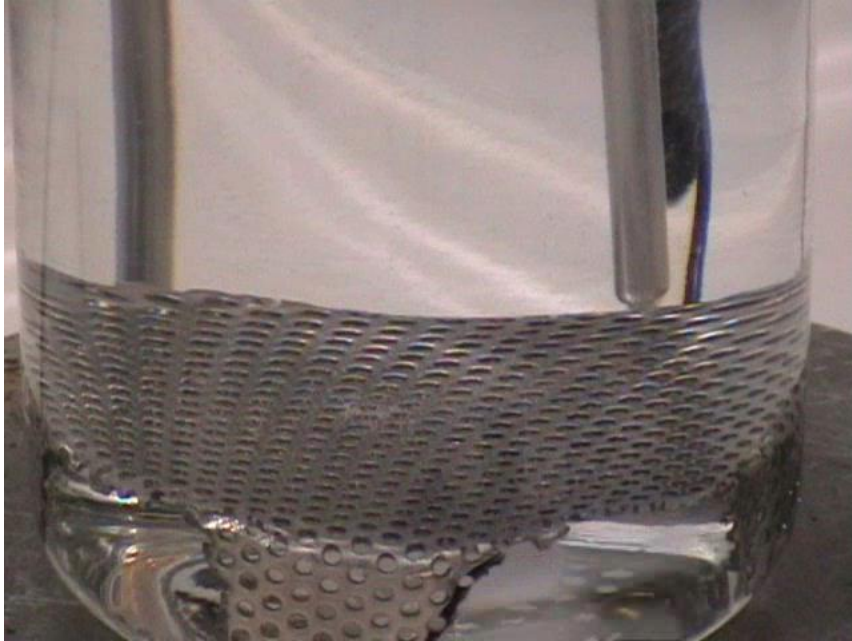


For prolonged residence time in the mouth we recommend galenIQ™ 720!

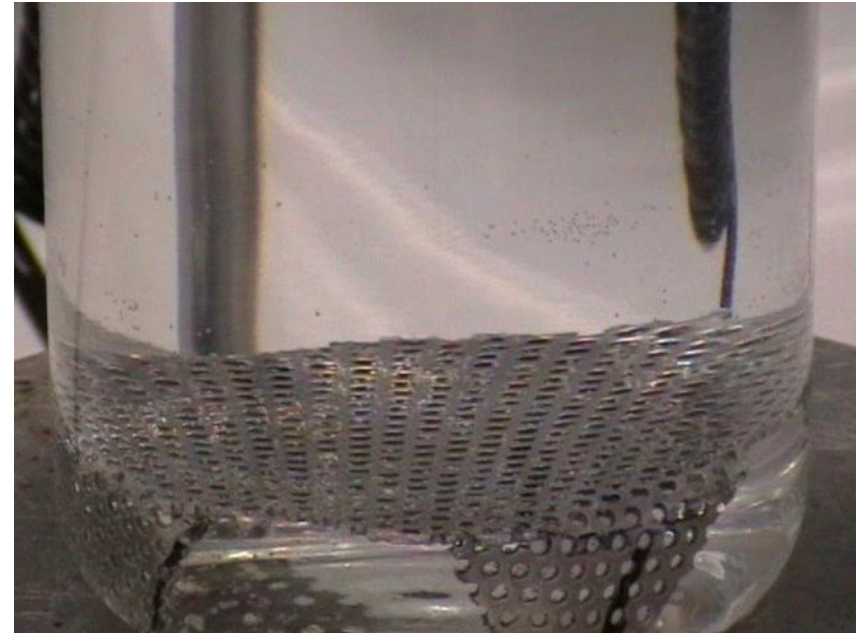
For all other kinds of tablets: **galenIQ™ 721**

# Disintegration of tablets

## Films



Disintegration of galenIQ™ 720  
based lozenge tablets



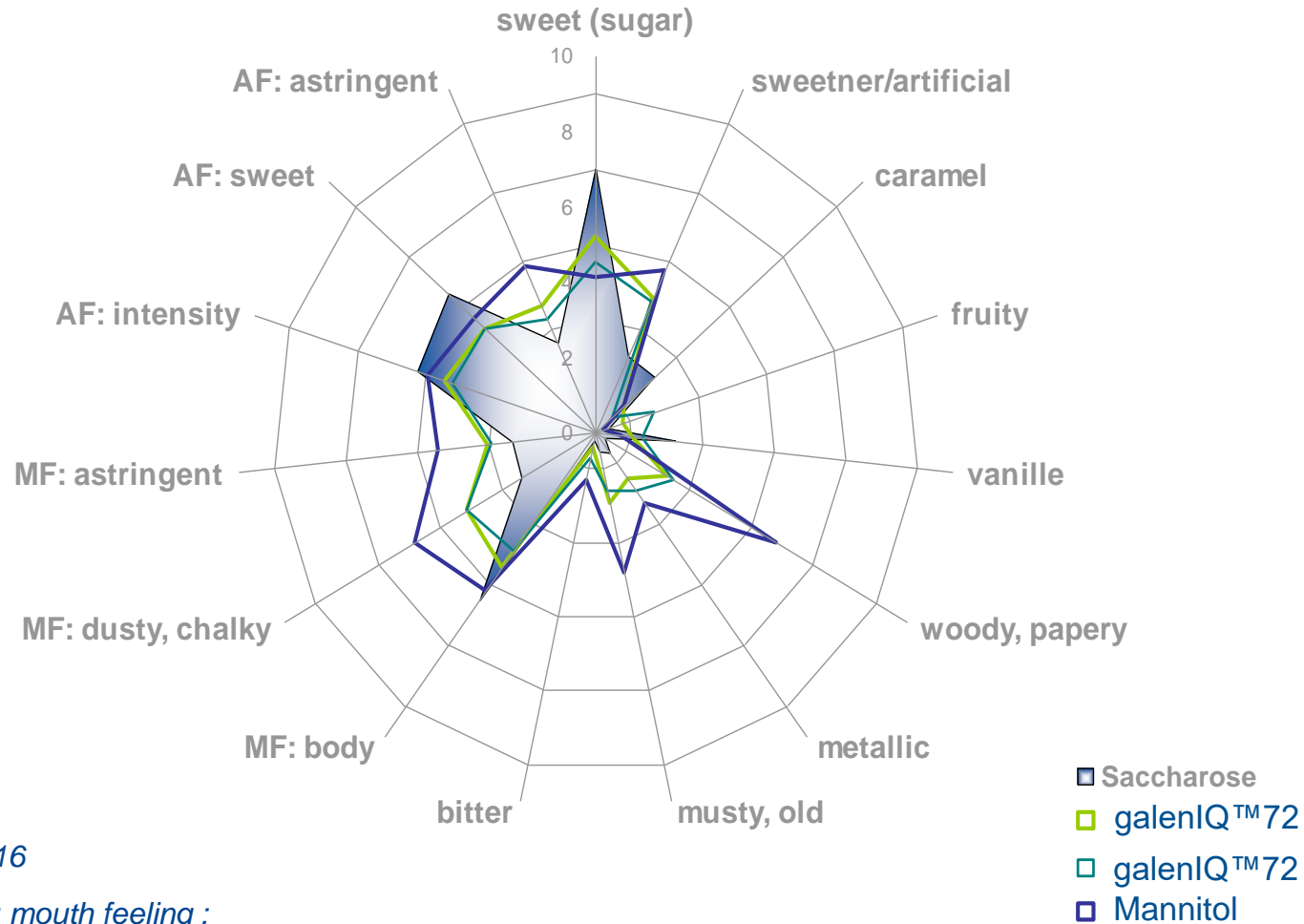
Disintegration of galenIQ™ 721  
based tablets



## galenIQ™ - pharmaceutical excipient



# Spiderplot of sensorial evaluation

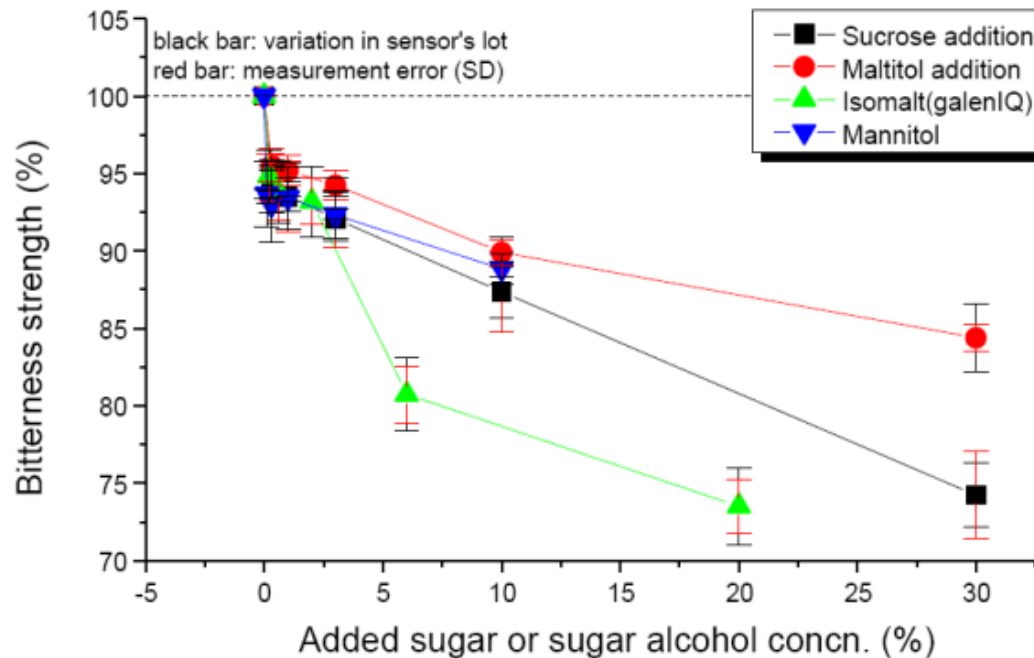


- $n=16$
- MF: mouth feeling ;  
AF: After Taste

# Characterization of the bitterness suppression in liquids galenIQ™ in comparison to sucrose, maltitol and mannitol

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## • Results



Electronic tongue system  
(Insent TS-5000Z)

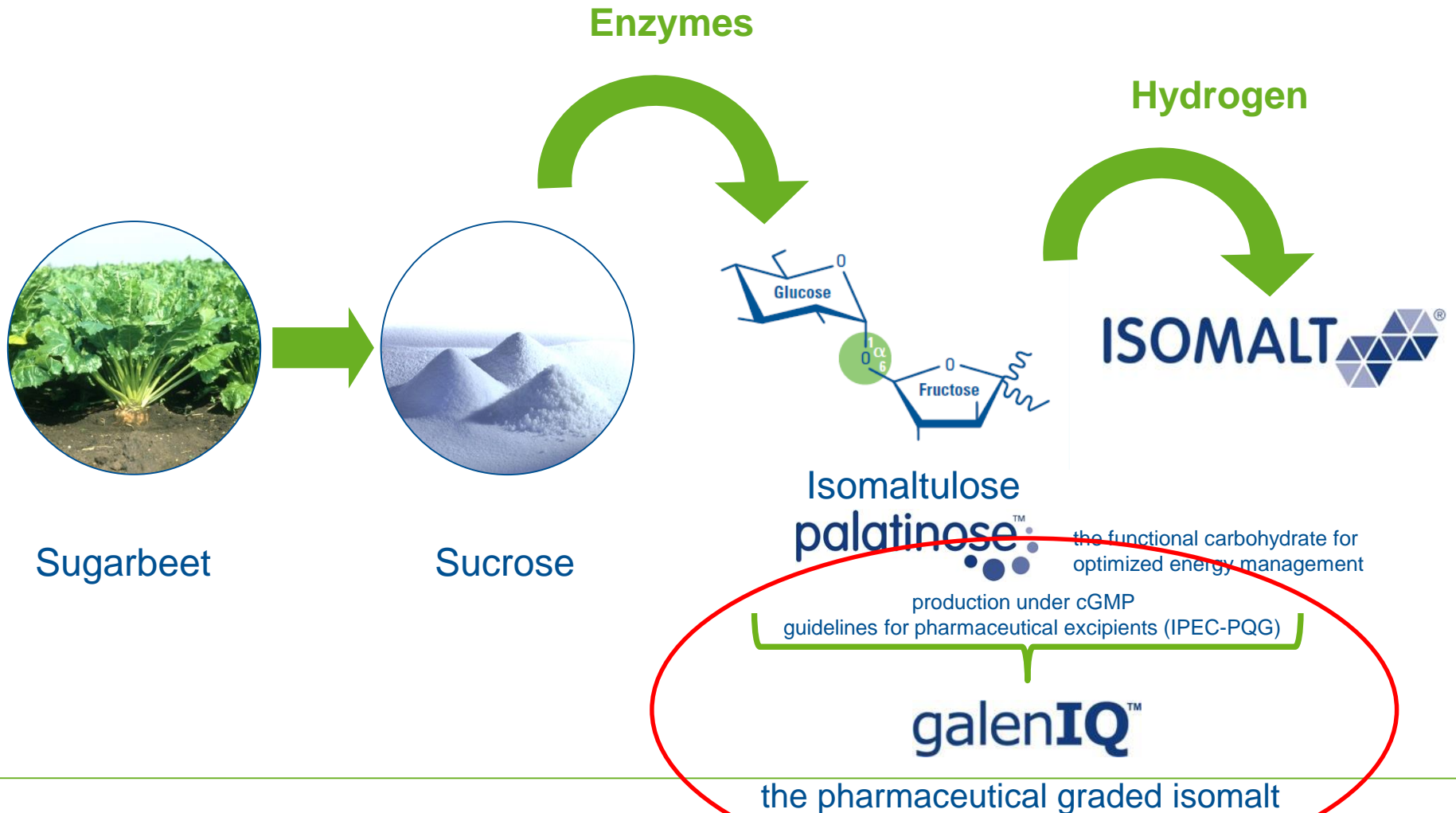
Figure Suppression effect by sugar and sugar alcohol using a bitterness sensor  
Bitter material: 0.1 mM quinine hydrochloride

**Tests with artificial sensors show that isomalt has a significantly better bitterness masking effect!**

## What is galenIQ™ and how can you use it?



# ISOMALT has a natural source



# History of ISOMALT

galenIQ™  
a brand of bene

1989

## BENEO-PALATINIT Production Site Offstein



galenIQ™

palatinose™

ISOMALT®



# History of ISOMALT

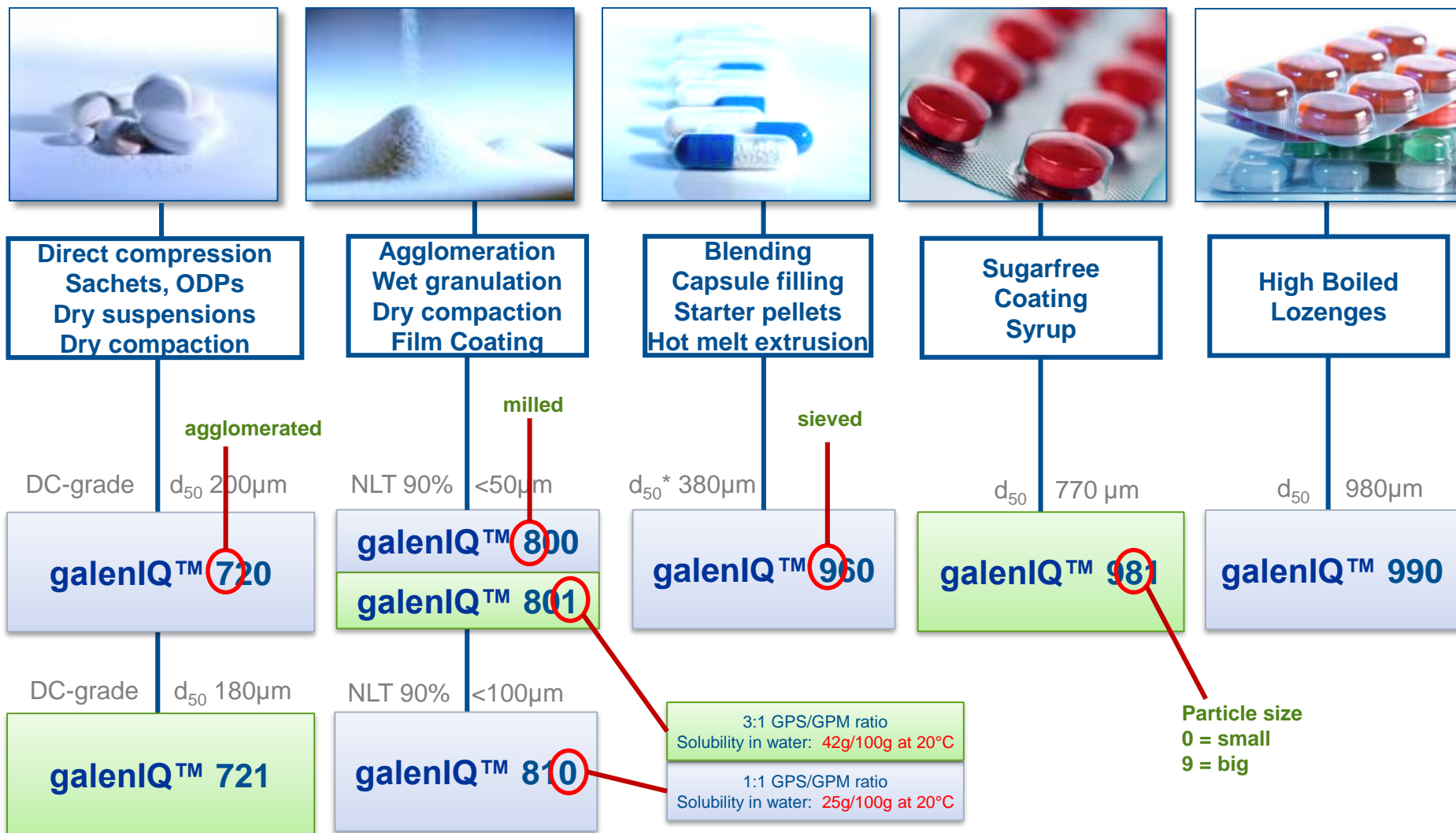


etc...

Today galenIQ™ complies with the Isomalt Monograph of  
→ Ph.Eur., BP, USP-NF, JPE + JP and IDL for China (Import drug licence)

# galenIQ™ (isomalt Ph.Eur., BP, USP-NF, JP) - Product Range

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\*Typical data within specification of the different galenIQ™ grades



# galenIQ™ 720 and 721

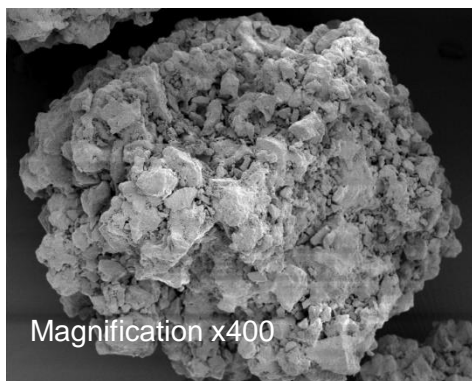
## galenIQ™ 720

■ Chemical composition: ~1:1 GPS/GPM

■ Solubility in water at 20°C: 25g/100g

■ Particle size distribution [μm]:

$d_{10}$  110 ;  $d_{50}$  260 ;  $d_{90}$  460



■ Specific surface area BET: 0,28 m²/g

■ Bulk density: 430 g/l

■ Hausner Factor: 1,12

■ Angle of response: 38°

■ Flowability (orifice 6mm): 60 s/100g

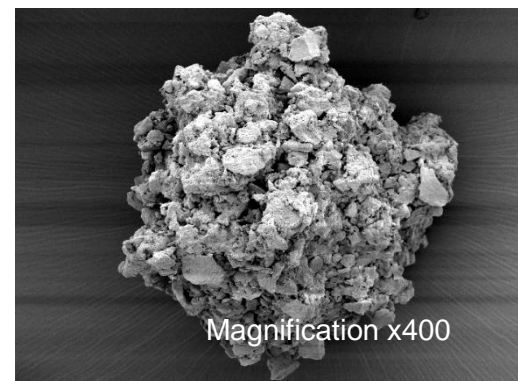
## galenIQ™ 721

■ Chemical composition: ~3:1 GPS/GPM

■ Solubility in water at 20°C: 42g/100g

■ Particle size distribution [μm]:

$d_{10}$  90 ;  $d_{50}$  220 ;  $d_{90}$  360



■ Specific surface area BET: 0,31 m²/g

■ Bulk density: 420 g/l

■ Hausner Factor: 1,07

■ Angle of response: 37°

■ Flowability (orifice 6mm): 62 s/100g

## Chewable tablets with Simethicone

Chewable tablet with Simethicone

galenIQ™ 721

Direct compression –  
galenIQ™ makes it easy

galenIQ™ 721

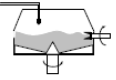


### 1. Formulation

Item	Component	Description	[w/w, %]
1	Simethicone*	Atypical Active	7
2	Isomalt (galenIQ™ 721)	Filler/Binder	88
3	Native Corn starch	Disintegrant	5

\*DOW CORNING® Q7-2243 LVA, Simethicone USP

### 2. Manufacture

Steps	Equipment
Weighing	Balance
Blending I	High Shear Granulator (HSG) (6 liter)
if HSG equipment is not available: Blending II	Tumbler mixer with fixed blending blades
Tabletting	Rotary tablet press

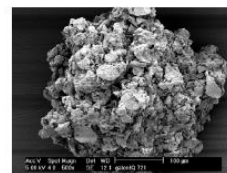
Workflow	Illustration	Process Parameter
1. Blending I		Rev. of Mixer [rpm] 250
Blend Items 1, 2 and 3 until a uniform mix is achieved. Pour in the oil carefully.		Rev. of Chopper [rpm] 0
		Time [min] 3
2. Alternative Blending II		Revolutions [rpm] 20
Blend Items 1, 2 and 3 until a uniform mix is achieved.		Time [min] 60
3. Compression		Compression force [kN] 7,9
Compress the blend into 600 mg round convex tablets.		Punch diameter [mm] 12

### 3. Tablet Properties (Mean values)

Property	Method	Unit	Result
Weight	(Ph.Eur.)	[mg]	603
Hardness	(Ph.Eur.)	[N]	60
Disintegration time	(USP/NF)	[s]	320
Friability	(Ph.Eur.)	[%]	0.4

#### Remarks

- Due to the presence of Corn starch no sticking to the punches occurs.
- Self-lubricating: due to the presence of Simethicone oil no further lubricants are necessary.
- Very good flowability of the mixture.
- Very good compressibility, no capping.
- galenIQ™ acts like a sponge which can absorb the oil:



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