## Be Phar Bel Manufacturing

DISCOVER OUR FIRST PRODUCT DEVELOPMENT
BASED ON ITS INNOVATIVE AND PATENDED
MMCR TECHNOLOGY.

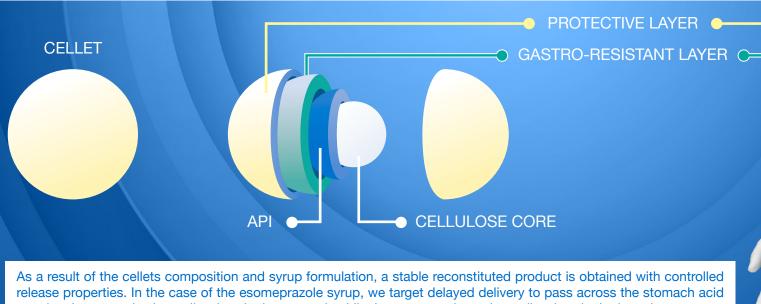
#### A GASTRO-RESISTANT SYRUP FOR THE TREATMENT OF PAEDIATRIC GERD

#### 1. THE MMCR TECHNOLOGY

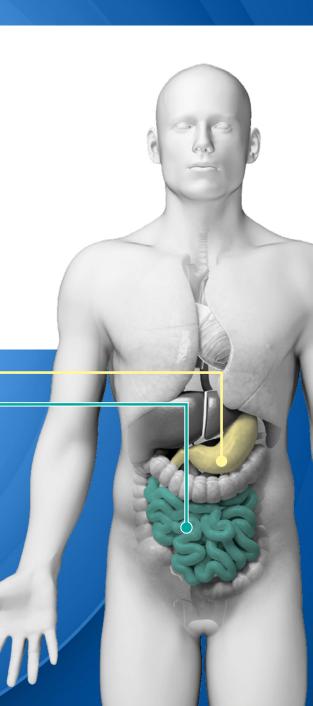
The MMCR Technology (Multi-layer Microparticles Controlled-Release system) is a groundbreaking patented technology:

- enabling the development of a sustained or delayed release syrup for any molecule that requires oral liquid administration.
- by delivering an Active Pharmaceutical Ingredient under the form of coated microparticles (cellets) suspended in a higly stable syrup.

#### GASTRO-RESISTANT CELLET IN ESOMEPRAZOLE SYRUP



attacks: the protective layer dissolves in the stomach while the gastro-resistant layer dissolves in the intestine.



#### 2. THE MEDICAL NEED

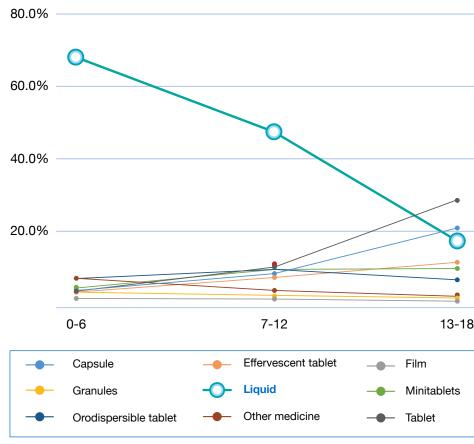
#### GASTROESOPHAGEAL REFLUX DISEASE (GERD)

- a chronic gastrointestinal disorder characterized by the regurgitation of gastric contents into the esophagus.
- one of the most commonly diagnosed digestive disorders estimated to affect **20% of the western population**<sup>(1)</sup>.

#### GERD AMONGST THE PAEDIATRIC POPULATION

- most commonly treated by PPI's (Proton Pump Inhibitors) as recommanded by ESPGHAN<sup>(2)</sup>.
- 3-6% of the population using PPI's are children aged 1-11 years old<sup>(3)</sup>.
- Represents 60 Million months of treatments worldwide and 21 Million in Europe<sup>(4)</sup>.
- Currently available PPI's dosage forms (solid caps and tabs) show strong limitations - particularly when swallowing impairments harm the ingestion process or when dosage adjustments are approximate – leading to efficacy or compliance issues.

### TRENDS OF DOSAGE FORMS' PERCEIVED PREFERENCE AMONG THREE AGE GROUPS



Source: Pharmaceutics 2021, 13, 730



<sup>(1)</sup> Gastroesophageal Reflux Disease: Catiele Antunes; Abdul Aleem; Sean A. Curtis

<sup>(2)</sup> European Society for Paediatric Gastroenterology Hepatology and Nutrition

<sup>(3)</sup> Source: Expert interviews, QYResearch 2021 and IQVIA 2021

<sup>(4)</sup> Data IQVIA



# COMPONENTS childproof cap Pipette for adapted dose administration Stick pack containing the coated cellets

#### **PREPARATION**



#### 3. THE ESOMEPRAZOLE SYRUP



**MEDICAL NEED** 

CONVENIENT

**GASTRO-RESISTANT** 

STABLE FORMULATION

**MULTI-DOSAGE** 

FLEXIBLE DOSAGE

**ACCESSIBLE** 

#### • The product presentation

- 125 ml or 100 ml syrup
- Stick pack with Esomeprazole cellets
- Concentration of the reconstituted syrup : 2 mg Esomeprazole per ml of syrup.
- Covers dosages from 5 mg to 20 mg esomeprazole
- Stability of the reconstituted syrup : maximum of 4 weeks when stored at 2-8°C
- Syrup and cellets shelf life: 36 months



#### 4. COMPARED TO COMPETITION

The in vitro study demonstrated that the reconstituted syrup has a similar dissolution profile to both reference products:

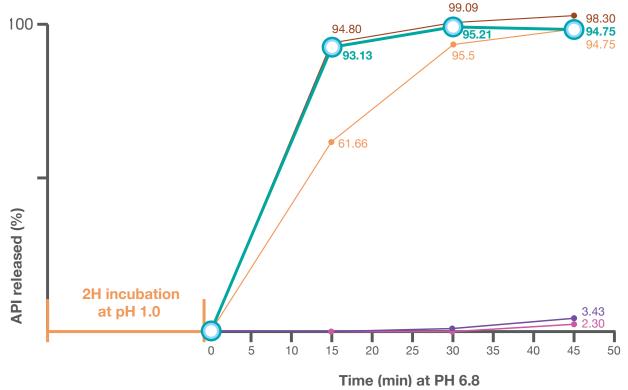


#### similarity factor F2:

91.8 vs. Nexiam® delayed release tablets 59.1 vs. Inexium® granulates in bags for drinkable suspension<sup>(1)</sup>

(1) Similarity factor calculated as per EMEA guideline.

#### % ESOM released vs time in buffer





Nexiam®: mean %API released (n=12)

MMCR SYRUP: mean % API released (n=6)

Inexium®: mean %API released (n=12)

Pedippi®: mean %API released (n=6)

SyrsPend®: mean %API released (n=6)

#### 5. THE DEVELOPMENT STATUS AND TIMELINE



Note: Indicated dates are expected completion dates



#### 6. SUMMARY

#### GASTRO-RESISTANT PPI LIQUID DOSAGE FORM

- Worldwide medical need for children 1-11 yrs
- Endorsed by Paediatricians and gastro-enterologists KOL
- Large market with high number of paediatric patients



#### **ESOMEPRAZOLE SYRUP**

- Unique esomeprazole liquid formulation in the market with innovative advantages
- Powered by groundbreaking patented MMCR Technology
- Similar in vitro dissolution profile to main reference products
- Next phase: scale up and bioequivalence (estimated market launch: 2026)
- Marketing and regulatory support from BePharBel Manufacturing



#### **FAST MARKET PENETRATION EXPECTED**

#### ARE YOU INTERESTED TO HEAR MORE?

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