Syngene

Putting Science to Work

Multidrug combo for companion animals

Development to commercialization of a complex palatable dosage form comprising 3 actives

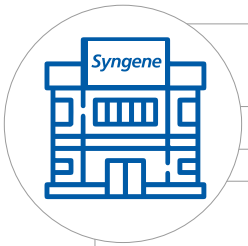
Business Problem

One of our leading multi-national animal healthcare clients was working on a novel three-drug combination product for the treatment of seasonal ticks in companion animals.

The client wanted to stabilise a low dose drug which is highly prone to hydrolytic degradation, and also ensure content uniformity of the active within the microgram dosage. The problem was unique and challenging, as the tabletting adjuvants were incompatible, and required our team to think outside the box to develop a stable formulation composition.

Key Program Features	Benefits
Scientific capability	• Stabilisation of the active (within the microgram dose which was prone to hydrolytic degradation), using novel polymer and a process which ensures content uniformity • Screening of different palatability strategies • Development via design of experiment approach and an appropriate design space • Development of discriminatory dissolution media • Use of novel analytical texture analysis to analyse the physical strength of tablets
Process improvements	• Process scale up from lab-scale to pilot-scale to commercial-scale using appropriate scale-up factors • Identification of critical process parameters and material attributes, to design the appropriate control strategy

Program Milestones



Technology Transfer & ICH stability

Transfer of manufacturing process and analytical methods (onsite)
5 storage conditions tested
98% Right first time analysis
Product stable for 2 years

Registration batches

2 API sources (24 batches)
8 placebo batches

Process Development and Scale Up

DoE studies to establish mfg processes
Scale-up to 500 kg scale

Mfg of Clinical batches

cGMP manufacturing of 6 active strengths and 1 placebo

Formulation Development

pH modifier, excipient & manufacturing process selection to address stability & uniformity

Analytical Method Development

Development and validation of 13 analytical methods including surrogate stability design

Target Product Profile

Hard Chew Tablets
3 APIs at extreme dose range

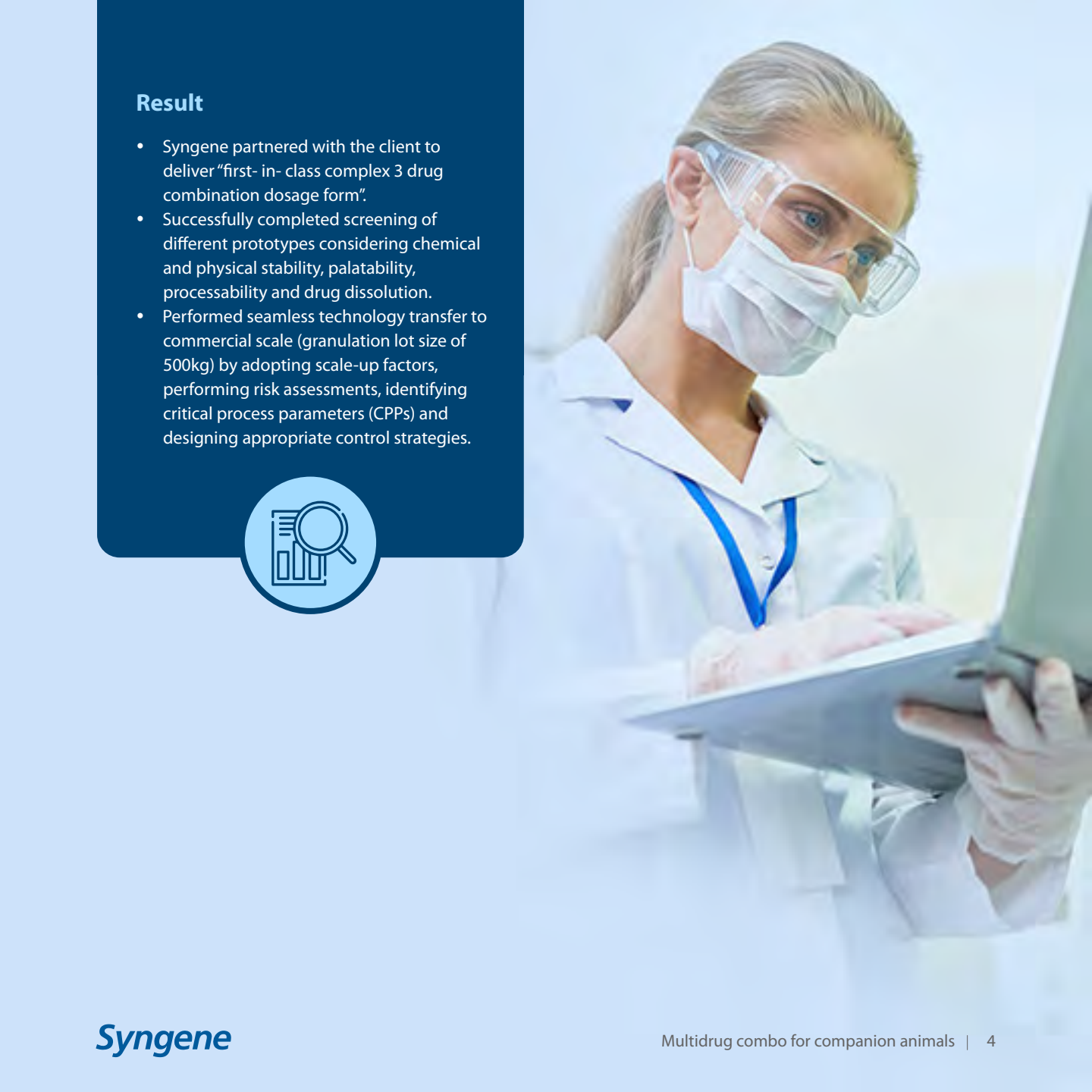
Key Success Parameters

- Drug-drug & drug-excipient compatibility
- Stability & Process selection
- Palatability and PK
- Surrogate stability (quick prototype selection)
- Informal stability & packaging selection
- Robust mfg process & scalability

Q1 Q2 Q3 Q4 Q5 Q6 Q7 Q8

Result

- Syngene partnered with the client to deliver "first- in- class complex 3 drug combination dosage form".
- Successfully completed screening of different prototypes considering chemical and physical stability, palatability, processability and drug dissolution.
- Performed seamless technology transfer to commercial scale (granulation lot size of 500kg) by adopting scale-up factors, performing risk assessments, identifying critical process parameters (CPPs) and designing appropriate control strategies.



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