MONASH University

MEDICINES MANUFACTURING INNOVATION CENTRE

MYLIQUITAB HOMECARE UNIT EVALUATION

Final Report Summary

REPORT PRODUCED FOR: MYLIQUITAB
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Medicines Manufacturing Innovation Centre
399 Royal Parade, Parkville, Vic 3052 Australia
T: +61 3 9903 0442
www.monash.edu/mmic
ABN 12 377 614 012 CRICOS Provider 00008C

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Study Summary

This executive summary describes the outcomes of an MMIC independent evaluation and characterisation of the myliquitab® Homecare tablet dispersion unit under intended/instructed use. The myliquitab Homecare unit comprises a system to disintegrate solid oral tablets into a fine liquid dispersion, to overcome dysphasia (difficulty in swallowing tablets), and to provide an alternative to manual tablet crushing.

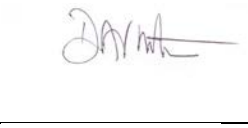
This study evaluated the dispersion of a range of representative oral dose tablets, including a range of dose strength and tablet size, indications, and water soluble and poorly soluble drugs. These tablets were all indicated as suitable to be crushed according to current Australian guidelines.

The main conclusions from this study were as follows:

- When operated as per the provided patient instructions, all tablets fully disintegrated into a liquid dispersion using myliquitab with the mean time observed of 3 minutes, and within a range of 1 to 7 minutes. As well as individual tablets, a mixture containing 5 different tablets was disintegrated, and no substantial change in liquid dispersion efficiency was observed for this mix over the disintegration of individual components.
- A water heating effect from ultra-sonication of approximately 4°C rise above ambient temperature was observed over this mean 3 minute time period and up to a 10°C rise over a 7 minute time period. This brief heating is not considered a significant risk to chemical stability over the timescale involved in dosing. In general, ultrasonic energy is widely used in analytical laboratories to facilitate compound dissolution, and in medical nebulisers to aerosolise drug solutions and is not considered to degrade conventional drug molecules over this exposure.
- Dose delivery from the dispensed tablets was observed to be effective. On simulated patient consumption, a maximum residual drug of 6% of dose was left in the beaker, which reduced to approximately 2% or less on a second rinse of the beaker, consequently resulting in 98% or greater of the drug dose delivered from the liquid dispersion.
- The flavouring agent had no observed effect on drug disintegration and was not considered likely to have any effect on dosing. The organoleptic effectiveness was not tested.
- Particle size analysis indicated dispersions were consistent, very small and suitable for oral swallowing delivery in each case

In summary, the myliquitab Homecare system consistently disintegrated all tested tablets, with or without flavouring, into a very fine dispersion that facilitated uniform dosing with minimal beaker residue loss. The system tested shows substantive advantages over traditional tablet crushing, as its operation (as per patient instruction) reduces tablet handling risks, reduces risk of drug loss, and removes arduous manual crushing operations.

SIGNATURES

Name	Position	Signature	Date
Prepared by	MMIC: Formulation and Process Lead		09/09/2017
D Morton			
Checked by	MMIC: Centre Manager		11/09/2017
P Wynne			

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