

Therapeutic Goods Administration
Scientific Evaluation Branch
Pharmaceutical Chemistry Section

Milestone 7 - Clearance Record

FOR INTERNAL USE ONLY

New generic medicine (Type D)

(type of submission)

tiotropium bromide

(drug substance – polymorphic form if present)

BRALTUS

(proposed trade name)

13 microgram Dry Powder for Inhalation, hard capsules

(dose form and strengths)

Teva Pharma Australia Pty Ltd

(sponsor/distributor if appropriate)

PM-2017-03103-1-5

(submission number)

[E18-211908](#)

(Chemistry file number)

Milestone 3 evaluation report: [D18-10408790](#)

Milestone 5 report [D18-10785551](#)

Post-Milestone 5 report [D18-10949278](#)

Recommendation and Clearance

Approval is recommended from a pharmaceutical chemistry perspective. *However, the labels should be amended to show the delivered dose and metered dose in similar prominence as below:*

Braltus

Tiotropium (as bromide)

13 microgram metered dose

10 microgram delivered dose

The following details relate to this submission:

Topic	Details	Acceptance reference
Trade names	The tradenames are: BRALTUS	D18-10130800
GMP	All clearances are valid until at least 29 March 2019	Not applicable
Product Information (PI)	PIs supplied with the post-milestone 5 response are acceptable from a chemistry perspective. However, it should be noted that clinical issues have been identified.	e002646 (0004) - Product information - clean
Labels	The labels supplied with the post-milestone 5 response are acceptable. These were considered compliant with TGO91. <i>However, please note suggestions for the labels above.</i>	e002646 (0004) - Label mock-ups and specimens - Carton - clean
PARs	The PARs are acceptable from a PCS perspective	Not applicable.
Drug substance specifications of API manufacturer	There are no issues with the DMF from [REDACTED]	E17-24557
Drug substance specifications of finished product manufacturer	These were accepted after review of the milestone 5 response	e002646 (0004) - Specification
Finished product specifications	These were accepted after review of the milestone 5 response	e002646 (0004) - Specifications - AU
Shelf life	24 months. Store below 25°C. Keep the bottle tightly closed. Store in the original package to protect from moisture. Do not refrigerate or freeze. Avoid storage in direct sunlight or heat.	MS 3: D18-10636968
Container Safety	Not applicable	Not applicable
Sterility	Not applicable	Not applicable
Endotoxin	Not applicable	Not applicable
RMP	<i>Pending</i>	D18-10950495


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3 September 2018