

Certificate of Conformance

Product	SPIRIVA RESPIMAT 4ML	CSA3
Article No. / Lot No.	59112520 / 002560	

Marketing Authorization No.	F-17708, 29123-12-09
Active Ingredients / Strength	tiotropium bromide monohydrate / 2,5 µg
Dosage form	solution for inhalation for respimat
Container Type	Plastic Bottle with Lock
Order-No.	90265486
BIX No.	112520
BIX Version	14
Quantity	20.499 Pieces
Date of Manufacture	21 MAR 2020
Date of Expiry	31 MAR 2023
Bulk Product Article No.	67752
Bulk Product Lot No.	002560
MDS	81485_P100AM0103/0301/, 0401/0501/0802 P330AM0103/0104/0401/0602, /0801 81485-GC15AM0101/0201
TS	Ecuador: R1TS-592V2 Chile: R1TS-592V2

I hereby certify that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries.

Remarks:

Released for Chile and Ecuador
 Additional MDS documents: 81485-p100am0402, 81485-p330am0802
 API Tiotropium bromide/ API Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Straße 173, 55216 Ingelheim am Rhein/ API Manufacturer Country: Germany/ API Batch number 1088464 & 1088462

This certificate has been signed 17 JUN 2020 15:15:06 electronically by Bärbel Panter (PANTER) (Qualified Person, Quality Assurance).