

Certificado de Libertação de Lote
Batch Release Certificate

Produto/Product: MEMANTINA MEMANVITAE 10 mg 56 cpr

AIM do Produto/Marketing Authorisation N.º: F-25036

País Importador/Importing Country: Chile

Código SAP/SAP Code: 5234582

Lote/Batch: PL1286A

Lote Origem/Batch Bulk: PL1286

C.Análise/C.Analysis: 000000132105

Data Fabrico/Manufacturing Date: 12.2019

Data Validade/Expiry Date: 12.2022

Quantidade/Quantity: 8,609 CX

Data de Libertação/Release Date: 2020.02.28

Desvios maiores ou críticos durante a produção/Major or critical deviation during manufacture:


(X) Nenhum/None () Relatório de desvio/Deviation report : —

Observações/Remarks:

AP's Manufacturing Authorization /GMP N.º: F036/001/2018 & F036/S1/MH/001/2018

Certifico que a informação acima é autêntica e correcta. Este lote de produto foi produzido, incluindo acondicionamento/etiquetagem e controlo de qualidade, no local de fabrico acima mencionado de acordo com os requisitos das Boas Práticas de Fabrico das Autoridades Reguladoras Nacionais e de acordo com as especificações da Autorização de Comercialização do país importador. Os registos de fabrico, acondicionamento e de análise foram revistos e considerados como estando em conformidade com as GMP.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above-mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.



Raquel Sobral
Direcção Técnica / Qualified Person

Certificate of Analysis

R/PGI.09.04/02

Certificate/Version: MEMAN10_000 000001

Material: 5234582

Description: MEMANTINA MEMANVITAE 10 mg 56 cpr

Manufacture Date: 2019.12.11

Expiry Date: 12.2022

Bulk Batch: PL1286

API Batch: M190300013, M190300083

Method: MAPA-MEMC-04-000010-0-B11-000-152-02

Reference: 302222

Batch: PL1286A

CoA: 000000132105

Analysis Date: 2020.02.28

Tests	Specifications	Results
General Analysis		
Appearance		Complies
Oblong biconvex white film-coated tablets bearing a break mark.		
Resistance to crushing	> = 70 N	164 N
Disintegration	< = 15 min	1 min
Assay	95.0 - 105.0 %	97.2 %
Identification of active substance		
Identification - GC (FID)	Positive	Positive
Average mass / Uniformity of mass		
Average Mass (AM) \pm 5%	213.2 - 235.6 mg	228.5 mg
n=20: AM \pm 7,5%	18 - 20	20
n=20: AM \pm 15%	20 - 20	20
Subdivision of tablets		
n=30: Average Mass \pm 15%	29 - 30	30
n=30: Average Mass \pm 25%	30 - 30	30
Uniformity of dosage units		
AV (n=10)	< = 15.0	4.3
Dissolution Q = 80 %, 15 min.		
S1 (n=6): individual results	> = 85 %	98.4 %
S1 (n=6): individual results	> = 85 %	100.2 %
S1 (n=6): individual results	> = 85 %	95.1 %
S1 (n=6): individual results	> = 85 %	98.3 %
S1 (n=6): individual results	> = 85 %	98.5 %
S1 (n=6): individual results	> = 85 %	103.3 %
S1 (n=6): average	> = 80 %	99 %
Related Compounds		
ADMA Impurity	< = 0.2 %	n.d.
Unspecified Impurities (Max. Indiv.)	< = 0.2 %	n.d.
Total impurities	< = 1.0 %	n.d.




Certificate of Analysis

R/PGI.09.04/02

Certificate/Version: MEMAN10_000 000001**Material:** 5234582**Description:** MEMANTINA MEMANVITAE 10 mg 56 cpr**Manufacture Date:** 2019.12.11**Expiry Date:** 12.2022**Bulk Batch:** PL1286**API Batch:** M190300013, M190300083**Method:** MAPA-MEMC-04-000010-0-B11-000-152-02**Reference:** 302222**Batch:** PL1286A**CoA:** 000000132105**Analysis Date:** 2020.02.28

Tests	Specifications	Results
-------	----------------	---------

Remarks: n.d. - not detected.**Decision:** Approved**Decision Date:** 2020.02.28


RAQUEL SOBRAL
Quality Control Manager