

Certificado de Libertação de Lote
Batch Release Certificate

Produto/Product: ARIPIPAZOL ARIVITAE 10mg 28cpr

AIM do Produto/Marketing Authorisation N.º: F-23344/17

País Importador/Importing Country: Chile

Código SAP/SAP Code: 5238724

Lote/Batch: SA0041E

Lote Origem/Batch Bulk: SA0041

C.Análise/C.Analysis: 143305

Data Fabrico/Manufacturing Date: 01.2021

Data Validade/Expiry Date: 01.2024

Quantidade/Quantity: 7,099 CX

Data de Libertação/Release Date: 2021.03.19

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

(☒) 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: ARIPIPR_000 000001

Material: 5238724

Description: ARIPIPRAZOL ARIVITAE 10mg 28cpr

Manufacture Date: 2021.01.14

Expiry Date: 01.2024

Bulk Batch: SA0041

API Batch: M200900147, M200900146, M201200017

Method: MAPA-ARIP-03-000010-0-B5-000-152-01

Reference: 302251

Batch: SA0041E

CoA: 143305

Analysis Date: 2021.03.18

Tests	Specifications	Results
General Analysis		
Appearance	Elliptic shallow convex pink tablets	Complies
Resistance to crushing	30 - 120 N	60 N
Water content (KF)	< = 6 %	4 %
Disintegration	< = 15 min	2 min
Average Mass and Unif. of mass		
Average Mass (AM) $\pm$ 5,0%	91.9 - 101.5 mg	97.4 mg
n=20: AM $\pm$ 7,5%	18 - 20	20
n=20: AM $\pm$ 15%	20 - 20	20
Unif. dosage units		
AV (n=10)	< = 15.0	5.1
Ident. and assay		
Identification - HPLC-RT		Positive
Positive. Retention time of test solution same as reference solution		
Identification - HPLC-DAD		Positive
Positive. Spectrum of test solution same as reference solution		
Assay	95.0 - 105.0 %	101.7 %
Identification iron oxide	Positive	Positive
Dissolution Q=80%, 30 min		
S1 (n=6): individual results	> = 85 %	101.9 %
S1 (n=6): individual results	> = 85 %	100.2 %
S1 (n=6): individual results	> = 85 %	99.9 %
S1 (n=6): individual results	> = 85 %	100.4 %
S1 (n=6): individual results	> = 85 %	100.8 %
S1 (n=6): individual results	> = 85 %	100.2 %
S1 (n=6): average	> = 80 %	101 %
Related Compounds		
Impurity B	< = 0.2 %	n.d.
Impurity BBQ	< = 0.2 %	n.d.
Single largest unspecified impurity	< = 0.2 %	0.03 %
Total impurities	< = 1 %	0.08 %
Microbiologic Control		
Total aerobic microbial count (TAMC)	< = 1000 cfu/g	< 10 cfu/g
Total combined yeast/mould count (TYMC)	< = 100 cfu/g	< 10 cfu/g
Escherichia coli	Absent/g	Absent/g



Certificate of Analysis

R/PGI.09.04/02

Certificate/Version: ARIPIPR_000 000001**Material:** 5238724**Description:** ARIPIPRAZOL ARIVITAE 10mg 28cpr**Manufacture Date:** 2021.01.14**Expiry Date:** 01.2024**Bulk Batch:** SA0041**API Batch:** M200900147, M200900146, M201200017**Method:** MAPA-ARIP-03-000010-0-B5-000-152-01**Reference:** 302251**Batch:** SA0041E**CoA:** 143305**Analysis Date:** 2021.03.18

Tests	Specifications	Results
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Remarks: n.d. - not detected.**Decision:** Approved**Decision Date:** 2021.03.18

RAQUEL SOBRAL
Quality Control Manager