

Certificado de Libertação de Lote
Batch Release Certificate

Produto/Product: IRBESARTAN IRBEVITAE 150mg 28 cpr

AIM do Produto/Marketing Authorisation N.º: F-21513/14

País Importador/Importing Country: Chile

Código SAP/SAP Code: 5229271

Lote/Batch: RG0922A

Lote Origem/Batch Bulk: RG0922

C.Análise/C.Analysis: 000000138006

Data Fabrico/Manufacturing Date: 07.2020

Data Validade/Expiry Date: 07.2023

Quantidade/Quantity: 14,160 CX

Data de Libertação/Release Date: 2020.09.11

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: IRBESART_000 000001

Material: 5229271

Description: IRBESARTAN IRBEVITAE 150mg 28 cpr

Manufacture Date: 2020.07.27

Expiry Date: 07.2023

Bulk Batch: RG0922

API Batch: M200500035

Method: MAPA-IRBE-04-000150-0-B3-000-152-01

Reference: 301876

Batch: RG0922A

CoA: 000000138006

Analysis Date: 2020.09.11

Tests	Specifications	Results
General Analysis		
Appearance		Complies
White, oblong, convex film-coated tablets scored on one side		
Resistance to crushing	140 - 240 N	190 N
Disintegration	<= 15 min	8 min
Water content (KF)	<= 3.0 %	2.2 %
AM and Unif. of mass		
Average Mass (AM) $\pm$ 5%	244.6 - 270.4 mg	258.0 mg
n=20: AM $\pm$ 5%	18 - 20	20
n=20: AM $\pm$ 10%	20 - 20	20
Unif. dosage units		
AV (n=10)	<= 15.0	2.5
Divisibility		
n=30: Average Mass $\pm$ 15%	29 - 30	30
n=30: Average Mass $\pm$ 25%	30 - 30	30
Ident. and assay		
Identification - HPLC-RT		Positive
Positive. Retention time of test solution same as reference solution		
Assay	95.0 - 105.0 %	100.4 %
Identification - HPLC-DAD		Positive
Positive. Spectrum of test solution same as reference solution		
Identification titanium dioxide	Positive	Positive
Dissolution Q=80%, 30 min.		
S1 (n=6): individual results	>= 85 %	102.0 %
S1 (n=6): individual results	>= 85 %	100.2 %
S1 (n=6): individual results	>= 85 %	101.7 %
S1 (n=6): individual results	>= 85 %	102.0 %
S1 (n=6): individual results	>= 85 %	102.9 %
S1 (n=6): individual results	>= 85 %	101.0 %
S1 (n=6): average	>= 80 %	102 %
Related Compounds		
IRB Diamide	<= 0.2 %	n.d.
Unknown Impurities (Max.Individual)	<= 0.2 %	< 0.02 %
Total impurities	<= 1.0 %	n.q.
Microbiological Quality		
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



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Tests	Specifications	Results
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Remarks: n.d. - not detected ; n.q. - not quantified.

Decision: Approved

Decision Date: 2020.09.11



RAQUEL SOBRAL
Quality Control Manager