

CERTIFICATE OF ANALYSIS

Date
14-Nov-2016

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Creon 10000 20cap

Material
1072658

Batch
54027

Prod. date
08.2016

Expiry date
07.2019

Characteristic	Unit	Result	Specification
Appearance bi-coloured hard gelatin capsules size 2 with brown opaque cap and colourless transparent body filled with brownish pellets		complies	see characteristic
Ident.: Amylase (enzyme activity test)		positive ident.	Positive identification
Ident.: Lipase (enzyme activity test)		positive ident.	Positive identification
Ident.: Proteases (enzyme activity test)		positive ident.	Positive identification
Uniformity of dosage units (Mass varia.) L1 = 15.0% , L2 = 25.0% acceptance value = k*s and M=X(mean)		complies	complies to Ph.Eur.
Assay: Amylase	PhEurU/cps	12510	>= 8000
Assay: Lipase	PhEurU/cps	11459	11000 .. 16500
Assay: Proteases	PhEurU/cps	747	>= 600
Water content of pellets	%	3.5	<= 4.0
Residual solvents: Isopropyl alcohol	%	0.1	<= 0.5
Residual solvents: Acetone	%	0.3	<= 0.5
Dissolution within 30 min: Q = NLT 80 %		complies	complies to Ph.Eur.
Dissolution within 30 min: Mean value	%	110	---
Disintegration time (Water)	min.	3	<= 15
Total aerobic microbial count (TAMC)	cfu/g	110	<= 10000
Total combined yeast/moulds count (TYMC)	cfu/g	< 10	<= 100
Bile-tolerant gram-negative bacteria	/g	< 10	<= 100
Salmonella		absent / 10 g	absent / 10 g
Escherichia coli		absent / 1 g	absent / 1 g
Staphylococcus aureus		absent / 1 g	absent / 1 g

Date of manufacture (DD.MM.YYYY): 15.08.2016

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Analytical test methods listed in specification document (allocation number in SOLID see below):

<u>Test</u>	<u>Test method</u>
Appearance	visual examination
Identification	Ph.Eur. / SOLID 0000082709
Uniformity of dosage units (mass variation)	Ph.Eur. 2.9.40
Assay	SOLID 0000082709
Water content of pellets	SOLID 0000082711
Residual solvents	P0000101
Dissolution test	SOLID 0000088309
Disintegration of capsule	Ph.Eur. 2.9.1
Total aerobic microbial count TAMC	Ph.Eur. 2.6.12
Total combined yeast/moulds count TYMC	Ph.Eur. 2.6.12
Bile-tolerant gram-negative bacteria	Ph.Eur. 2.6.13
Salmonella	Ph.Eur. 2.6.13
Escherichia coli	Ph.Eur. 2.6.13
Staphylococcus aureus	Ph.Eur. 2.6.13

The regulatory compliance regards the following countries:

Chile	RegN° F-14795	SpecN° SOLID 0000104693 Version 1.0
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3 of 3**Creon 10000 20cap**Material
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07.2019**CERTIFICATE OF CONFORMITY**Importing country: see page 2
Marketing Authorization No.: see page 2Strength/potency: Each capsule contains 150 mg Pancreatin as API
corresponding to not less than:
Lipase 10,000 Ph.Eur. units
Amylase 8,000 Ph.Eur. units
Proteases 600 Ph.Eur. unitsDosage form: Hard gelatin capsule with 249.5 mg enteric-coated pellets
Package size: 20 capsules
Package type: HDPE bottle with PP cap in a folding carton box
08.11.2016 TL Korrektur "41404" auf "41401"Name/address of manufacturer:
Abbott Laboratories GmbH
Werk Neustadt
Justus-von-Liebig-Str. 33
D-31535 Neustadt a. Rbge.
Germany
Manufacturer's License Number: DE_NI_02_MIA_2016_0007/41401/H-144
Certificate of GMP Compliance: DE_NI_02_GMP_2016_0001Results of Analysis: see page 1
Test methods: see page 2
Comments: N/A

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.

This certificate was generated by a validated system and signed electronically.

14.11.2016 / 13:24:08 CET e-sign: David Schwarzer, Qualified Person,
Certificate checked and approved

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