

CERTIFICATE OF ANALYSIS 2003229

ItemNo.: 0301 0001
 Description: Shellac SSB 55 PHARMA FL
 Batch No. 138100
 Date of manufacture: 01.2012
 Date of Expiry: 01.2014

Specifications	Methods of analysis	Nominal values	Unit	Actual values
Chemical-physical analysis				
Specific pharmaceutical analysis	Pharmacopeia			see attachment
Colour index	Lovibond PRS-scale 20% in ethanol	1 - 1,75		1,75
Microbiological analysis				
Mikrobiological parameters	Ph. Eur., Pharmaceutical preparations, cat. 3B			see attachment
* Parameter, which is tested regularly but not batchwise within the scope of final inspection.				
** has to meet the requirements of the monograph.				

Remarks:

The above identified product conforms to the agreed standard as specified in all requirements. The supplier guarantees to keep samples of any lot which had been inspected.
 Above information do not relieve the purchaser from controlling the product on delivery.

Status: release

Bremen, 08.02.2012

i.A. Mikli's

 Quality Control

i.A. Senkole

 Quality Assurance

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Expert on Official Counter Samples by the State of Bremen

QSI GmbH - Flughafendamm 9a - D-28199 Bremen

Stroeever GmbH & Co. KG

Printed: 8-Feb-2012
209/2

Postfach 15 03 51
D-28093 Bremen

Date: 08-Feb-2012

Order: 178357/20196

Sample-No.: 71789

Date: 31-Jan-2012

Sample: 31-Jan-2012

Temp.: RT

Product: Diverse

Packaging: diverse

Kind: Schellack / shellac

Seal: ohne/without

Label: MB-Nr.: 5332, 200 g Schellack SSB 55 PHARMA FL, Charge Nr.: 138100, MB-Order:
5332, 200 g shellac SSB 55 PHARMA FL, Lot: 138100

The test results are exclusively related to the items tested for this sample. Method and measurement uncertainty details are available upon request. This report is allowed to be copied completely and unchanged but not in extracts. Test period: order date till date of this report

Chemical-physical analysis (9006)

Shellac, Ph.Eur. 7.0, 2011 "Shellac/Lacca", USP 35 NF 30 "Shellac", JP XV "Purified Shellac"

Test	(Method)	Nominal value	Result
Appearance	Ph. Eur., JP	*	: entspricht/ according
Solubility	Ph. Eur., JP	*	: entspricht/ according
Loss on drying (Dew. Orange Shellac*/Ref. Bleached Shellac**)	Ph. Eur., USP, JP	max. 2,0%*/6,0%**	: 1,4
Identification A, TLC	Ph. Eur. 2.2.27	*	: entspricht/ according
Identification B, TLC	Ph. Eur. 2.2.27	*	: entspricht/ according
Colophony, TLC	Ph. Eur. 2.2.27	*	: entspricht/ according
Identification	USP	*	: entspricht/ according
Arsenic	Ph. Eur. 2.4.2 A	max. 3 ppm	: <3
Arsenic	JP	max. 5 ppm	: <5
Heavy metals	Ph. Eur., USP, JP	max. 10 ppm	: <10
Rosin	USP, JP	*	: entspricht/ according
Wax (Dewaxed Or. Shellac/ ref. bleached shellac)	USP, JP	max. 0,2 %	: 0,02

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Amtsgericht Bremen HRB 18842
Managing Director: Gudrun Beckh
Michael Lambert - Dr. Cord Lüllmann

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Acid value	Ph. Eur. 2.5.1	65 - 95	: 73
Acid value (Dewaxed Or. Shellac*/Ref. Bleached Shellac**)	USP	71 - 79*/75 - 91**	: 73
Acid value (Purified Shellac*/White Shellac**)	JP	60 - 80*/65 - 90**	: 73
Total ash	JP	max. 1,0%	: 0,3
Ethanol-insoluble substances	JP	max. 2,0%	: 1,2
Chloride	JP "White Shellac"	max. 0,140%	: entfällt
Sulfate	JP "White Shellac"	max. 0,110%	: entfällt
Accordance with Ph. Eur.			: entspricht/ according
Accordance with USP			: entspricht/ according
Accordance with JP			: entspricht/ according

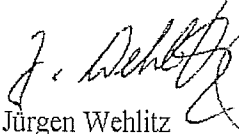
* = has to meet the requirements of the mentioned monograph; < = lower than


This examination is the basis for special decision guidance.

Quality Services International GmbH

Testmanager: Jürgen Wehlitz

Version 2 replacing version 1


Jürgen Wehlitz
Staatl. geprüfter Lebensmittelchemiker



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Stroeever GmbH & Co. KG

Printed: 6-Feb-2012
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Postfach 15 03 51
D-28093 Bremen

Date: 06-Feb-2012

Order: 178358/20196

Sample-No.: 71789

Date: 31-Jan-2012

Sample: 31-Jan-2012

Temp.: RT

Product: Diverse

Packaging: diverse

Kind: Schellack / shellac

Seal: ohne/without

Label: MB-Nr.: 5332, 200 g Schellack SSB 55 PHARMA FL, Charge Nr.: 138100, MB-Order: 5332, 200 g shellac SSB 55 PHARMA FL, Lot: 138100

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Microbiological analysis (52047)

Microbiology, Eur. Pharm. 7.0, 2011, table 5.1.4.1/5.1.4.2 (ex cat. 3B), Pharmaceutical Preparations

Test	permitted level*	
TAMC/g (2.6.12)	1000	: <10
Enterobacteria**/g (2.6.13)	100	: <10
E. coli/g (2.6.13)	negative	: negativ/negative
Staphylococcus aureus/g (2.6.13)	negative	: negativ/negative
Salmonella/10 g (2.6.13)	negative	: negativ/negative
TYMC/g (2.6.12)	100	: <10
Accordance with the microbiological requirements of Ph. Eur.		: entspricht/according

* for oral administration containing non-sterile substances; ** bile-tolerant gram-negative bacteria

Interpretation of permitted level (2.6.12): 100 = max 200, 1000 = max 2000

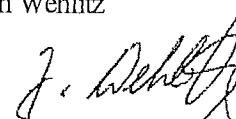
The sample is entspricht/according to the microbiological requirements of Ph. Eur. for pharmaceutical preparations.

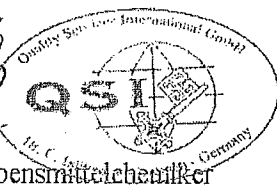
This examination is the basis for special decision guidance.

Quality Services International GmbH

Testmanager: Jürgen Wehlitz

Version 2 replacing version 1


Jürgen Wehlitz
Staatl. geprüfter Lebensmittelchemiker



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