



# RECHNUNG / INVOICE

Blatt / Page 1 / 1

Käufer / Purchaser	Versandanschrift / Shipping address
A.Menarini Asia-Pacific Holdings Pte.Ltd. #08-32 Mapletree Business City 30 Pasir Panjang Road  SG 117440 Singapore GST no. M90365359J	SPH KDL Health (Shanghai) Logistics Co.,Ltd WQQ PFTZ Shanghai USCI 91310000607396267B NO.286 Meiyue Road  CN 200131 Shanghai / China

Vertrags-Nr. / Contract no.	Kunden-Nr. / Customer no.	Debitor / Debitor	Ust.-Ident-Nr. / VAT ID no.	Rechnungs-Nr. / Invoice no.	Rechnungs-Datum / Date of invoice	Bitte bei Zahlungen und Rückfragen angeben / Please provide when paying or placing an inquiry.
A002987604	0000953342	95152		F003399615	1.03.24	

our VAT-Ident-no.: DE137202433

Kunden-Auftrags-Nr. / Customer order no.	Import-Lizenz-Nr. / Import licence no.	Zahlungsbedingungen / Terms of payment
1-006417, 1-006189, 1-006110		60 days at the end of the month
Versand-Datum / Shipping date	Transport-Art / Mode of transport	
6.03.24	by seafreight	
Kolli / Smallest unit		
cont.1 (pl.1-23,40'), cont.2 (pl.24-46,40')		
Markierung / Label	Lieferbasis / Bestimmungsort / Delivery terms, destination	
purchase order no.: 1-006417, -006189 -006110 product name case no. gross weight net weight	CIF Shanghai / China according to Incoterms 2010 Spezielle Hinweise / Special instructions  cont.3 (pl.47-69,40') cont.4 (pl.70-92,40')	

Nr. / No.	Menge / Quantity	Einheit / Unit	Artikelbezeichnung / Item description	Einzelpreis / Price per unit	Gesamtpreis / Total price
F152420	293.120,00	pks	Espumisan 30ml RBINVEPCN2005 HS-Code: 30049000 origin: Germany	0,87	255.014,40
F146229	61.862,00	pks	Zostex 1tbl RBINVZTXCN2004 HS-Code: 30049000 origin: Germany  Export of goods (§6(1) UStG). The supply is exempted from VAT (§4 No.1a UStG).	1,40	86.606,80

Warenwert / Value of goods	Steuerpflichtiger Betrag / Taxable value	MwSt.% / VAT%	MwSt. Betrag / VAT amount	Währung / Currency	Gesamtbetrag / Total amount
341.621,20				EUR	341.621,20
Volumen / Volume	Gewicht/kg Weight [kg]	Unterschrift / Signature	Stempel / Stamp	Skonto / Cash discount	Endbetrag / Final amount
97,15	B/gross 28.288,28 N/net 25.894,02				341.621,20

Postanschrift / Postal address

Berlin-Chemie AG

12485 Berlin, Germany

Telefon / Telephone +49 30 6707-0 (switchboard)

Telefax / Fax +49 30 6707-2777

**BERLIN-CHEMIE**  
**MENARINI**

BERLIN-CHEMIE AG

Glienicker Weg 125

12489 Berlin, Germany

www.berlin-chemie.de

**PACKLISTE / PACKING LIST****K002974755**

Blatt / Page 01/03

Käufer / Buyer	Zollstation / Customs point	Versandanschrift / Shipping to
A.Menarini Asia-Pacific Holdings Pte.Ltd. #08-32 Mapletree Business City  30 Pasir Panjang Road  SG 117440 Singapore GST no. M90365359J		SPH KDL Health (Shanghai) Logistics Co.,Ltd WGO PFTZ Shanghai USCI 91310000607396267B  NO.286 Meiyue Road  CN 200131 Shanghai / China

Vertrags-Nr. / Contract no.	Kunden-Nr. / Buyer no.	Rechnungs-Nr. / Number of invoice	Rechnungs-Datum / Date of invoice	Bitte bei Zahlungen und Rückfragen angeben / Please state in case of payments and inquiries.	+86 2138134929
A002987604	0000953342	F003399615	01.03.2024		

Kunden-Auftrags-Nr. / Purchase order no.	Import-Lizenz-Nr. / Import licence no.
1-006417, 1-006189, 1-006110	

Markierung / Marking	Versandhinweise / Shipping remarks / notify
purchase order no.: 1-006417, -006189 -006110 product name case no. gross weight net weight	by seafreight store between +15°C and +25°C
	Bestimmungsort / Place of destination / routing
	CN 200131 Shanghai / China
	Anzahl und Art der Packstücke / No. & kind of packing
	cont.1(pl.1-23,40'), cont.2(pl.24-46,40') cont.3(pl.47-69,40') cont.4(pl.70-92,40')

Pal.-Nr. Pal.-no.	Karton Cart.	Stck./Karton Packs/cart.	Gesamt Total	Einheit Unit	Artikelbezeichnung Description	Brutto / kg Gross / kg	Netto / kg Net / kg	Charge Batch no.	Haltbarkeit Expiry date
01-01	24	200	4.746	pks	Zostex 1tb1 RBINVZTXCN2004			31001M	31.01.26
02-02	8	200	1.600	pks	Zostex 1tb1 RBINVZTXCN2004			31001M	31.01.26
02-02	1	191	191	pks	Zostex 1tb1 RBINVZTXCN2004			31001M	31.01.26
02-02	1	191	191	pks	Zostex 1tb1 RBINVZTXCN2004			31001M	31.01.26
02-02	1	134	134	pks	Zostex 1tb1 RBINVZTXCN2004			31001M	31.01.26
	35	----	6.862	pks	SUMMARY - BATCH	170,470	122,560		

Volumen / Volume	Gewicht/kg / Weight/kg	Stempel / Unterschrift / Stamp / Signature	Datum / Date
97,150	gross 28288,278 net 25894,020		

Postanschrift / Postal address  
 Berlin-Chemie AG  
 12485 Berlin, Germany  
 Telefon / Telephone +49 30 6707-0 (switchboard)  
 Telefax / Fax +49 30 6707-2777



BERLIN-CHEMIE AG  
 Glienicker Weg 125  
 12489 Berlin, Germany

www.berlin-chemie.de

## PACKLISTE / PACKING LIST

K002974755

Blatt / Page 02/03

Pal.-Nr. Pal.-no.	Karton Cart.	Stck./Karton Packs/cart.	Gesamt Total	Einheit Unit	Artikelbezeichnung Description	Brutto / kg Gross / kg	Netto / kg Net / kg	Charge Batch no.	Haltbarkeit Expiry date
03-13	264	200	52.800	pkts	Zostex 1tbl RBINVZTXCN2004			33502A	30.09.26
14-14	11	200	2.200	pkts	Zostex 1tbl RBINVZTXCN2004			33502A	30.09.26
	275	----	55.000	pkts	SUMMARY - BATCH	1316,000	982,300		
	310	----	61.862	pkts	S U M M A R Y - - P R O D U C T - -	1486,470	1104,860		
15-23	216	160	34.560	pkts	Espumisan 30ml RBINVESPCN2005			34072A	30.11.26
24-38	360	160	57.600	pkts	Espumisan 30ml RBINVESPCN2005			34072A	30.11.26
39-39	15	160	2.400	pkts	Espumisan 30ml RBINVESPCN2005			34072A	30.11.26
	591	----	94.560	pkts	SUMMARY - BATCH	8644,180	7996,939		
40-46	168	160	26.880	pkts	Espumisan 30ml RBINVESPCN2005			34073A	30.11.26
47-64	432	160	69.120	pkts	Espumisan 30ml RBINVESPCN2005			34073A	30.11.26
65-65	3	160	480	pkts	Espumisan 30ml RBINVESPCN2005			34073A	30.11.26
	603	----	96.480	pkts	SUMMARY - BATCH	8825,850	8159,314		
66-69	96	160	15.360	pkts	Espumisan 30ml RBINVESPCN2005			34074A	30.11.26
70-89	480	160	76.800	pkts	Espumisan 30ml RBINVESPCN2005			34074A	30.11.26
90-90	14	160	2.240	pkts	Espumisan 30ml RBINVESPCN2005			34074A	30.11.26
	590	----	94.400	pkts	SUMMARY - BATCH	8630,088	7983,409		
91-92	48	160	7.680	pkts	Espumisan 30ml RBINVESPCN2005			34075A	30.11.26
	48	----	7.680	pkts	SUMMARY - BATCH	701,690	649,498		
	1.832	----	293.120	pkts	S U M M A R Y - - P R O D U C T - -	26801,808	24789,160		
					cont.1 gross weight: 4644,05 kg, net weight: 4027,60 kg, vol: 24,288 cont.2 gross weight: 7942,49 kg, net weight: 7347,44 kg, vol: 24,288 cont.3 gross weight: 7773,32 kg, net weight: 7185,06 kg, vol: 24,288 cont.4 gross weight: 7928,39 kg, net weight: 7333,91 kg, vol: 24,288				
					Wholesale distribution authorisation pursuant to Section 52a German Medicinal Products Act for Berlin-Chemie AG issued by the State Office of Health and Social Affairs Berlin on 27.05.2019 with file reference number				

Postanschrift / Postal address  
Berlin-Chemie AG  
12485 Berlin, Germany  
Telefon / Telephone +49 30 6707-0 (switchboard)  
Telefax / Fax +49 30 6707-2777



**BERLIN-CHEMIE**  
**MENARINI**

BERLIN-CHEMIE AG  
Glienicke Weg 125  
12489 Berlin, Germany

[www.berlin-chemie.de](http://www.berlin-chemie.de)


## PACKLISTE / PACKING LIST

K002974755

Blatt / Page

03/03

Pal.-Nr. Pal.-no.	Karton Cart.	Stck./Karton Packs/cart.	Gesamt Total	Einheit Unit	Artikelbezeichnung Description	Brutto / kg Gross / kg	Netto / kg Net / kg	Charge Batch no.	Haltbarkeit Expiry date
					5373/1-Berlin-Chemie-gh/2.				

EUROPÄISCHE GEMEINSCHAFT		VERFAHREN (1) EX   A   Bes. Umst. (S32)		MRN 24DE370128574417B0 		
Ausfuhrbegleitdokument	Versender/Ausführer (2) BERLIN CHEMIE Glienicker Weg 125 12489 Berlin DE		Nr. DE2762137		Ausstellungsdatum 06.03.2024 07:00 Uhr	
	Empfänger (8) SPH KDL Health (Shanghai) NO.286 Meiyue Road 200131 Shanghai / China CN		Nr.		A Ausfuhrzollstelle DE003701 Hauptzollamt Potsdam Zollamt Ludwigsfelde Genshagener Str. 27  14974 Ludwigsfelde	
	Anmelder/Vertreter (14) [1] BERLIN CHEMIE Glienicker Weg 125 12489 Berlin DE		Nr. DE2762137		Positionen (5) 2	
	Kennzeichen des Beförderungsmittels beim Abgang (18) Cosco Shipping Capri Corn				Packst. insgesamt (6) 92	
	Verkehrszweig an der Grenze (25) 1		Rohmasse (kg) (35) 28288,28		Bezugsnummer (7) 001_K002974755 / F003399615	
Ausgangszollstelle (29) DE004851		Nummer des Zollverschlusses (S28) Anzahl: -- --		Beförderungskosten, Code für die Zahlungshinweise (S29) H		
Verkehrsart (15) a) DE		Bestimmungsland (17) a) CN		Code für die zu durchfahrenden Länder (S13) DE, CN		
Warenort (30) Code für den Ort des Verladens bzw. des Verpackens: BC01		Vertreter der Person, die summ. Anm. abgibt (14b)				
Zeichen und Nummern - Container Nr. - Anzahl und Art		Päckchen und Warenbezeichnung (31)				
Siehe Liste der Positionen						

PRÜFUNG DURCH DIE ZOLLSTELLE	K PRÜFUNG DURCH DIE AUSGANGSSTELLE
Ergebnis:	Ankunftsdatum:
	Prüfung der Verschlüsse:
Frist (letzter Tag):	Bemerkungen:

## LISTE DER WARENPOSITIONEN - AUSFUHR

Vordrucke (3)

2

2

MRN 24DE370128574417B0



Pos.-Nr. (32)	Anzahl und Art der Packstücke, Zeichen und Nummern der Packstücke (31.1)	Warenbezeichnung (31.4)
Versender/Ausführer (2)	Empfänger (8)	
Kennzeichen des Beförderungsmittels beim Abgang (18)	Warennummer (33)	
Kennnummer der Sendung (Unique Consignment Ref. Nr.) (7)	Summarische Anmeldung/Vorpapier (40)	
Vorgelegte Unterlagen / Bescheinigungen (44.1)	Container-Nr. (31.3)	Nummer des Zollverschlusses (S28)
Besondere Vermerke (44.2)	Verfahren (37) Ausfuhrland (15a) Bestimmungsl. (17a) Rohmasse (kg) (35)	
UNDG (44.4)	Beförderungskosten, Code für die Zahlungsweise (S29)	Anmeldungsart (1) Statistischer Wert (46) Eigenmasse (kg) (38)
1	1. 92 PX, Palette Diverse	Zostex 125 mg 1 tablets
DE2762137 BERLIN CHEMIE Glienicker Weg 125 12489 Berlin (DE) Deutschland		
		30049000
		ohne
		OERU4277055 OERU4075408 FBIU505068 TEMU9298289
		1000 DE CN 28288,28
		1104,86
2	1. 0 PX, Palette Diverse	Espumisan L 40 mg/ml 1 x 30ml emulsion bottle (gla
DE2762137 BERLIN CHEMIE Glienicker Weg 125 12489 Berlin (DE) Deutschland		
		30049000
		ohne
		1000 DE CN 0
		24789,16



Genehmigung durch den Deutschen Industrie- und Handelskammertag e.V. (DIHK) am 14. April 2016





# BERLIN-CHEMIE MENARINI

## Analysenzertifikat

## Certificate of Analysis

## Сертификат анализа

Product / 产品:  
MENARINI Code no. / MENARINI 代码编号:  
BC Code no. / BC代码编号:  
Batch no. / 批号: 31001M  
Date of Manufacture / 生产日期: 02/2023  
Date of Batch Release / 批放行日期: 02/02/2024

检验报告  
Zostex ® / 溴夫定片  
RBINVZTXCN2004  
F146229

Date of Expiry / 有效期: 01/2026

Item / 项目	Specification / 质量标准	Result / 结果
<u>Appearance / 性状</u>	White or off-white tablets 白色或类白色片	conforms 符合
Average mass / 平均质量	245 mg $\pm$ 5 %	245. mg
<u>Testing of the dosage form</u> <u>剂型的检验</u>		
Uniformity of dosage units / 剂量单位的均匀度	Complies with Ph.Eur. 2.9.40 by mass variation / 符合欧洲药典的要求2.9.40 质量差异	conforms 符合
Friability / 脆碎度	not more than 1 % 不超过1%	< 1. %
Dissolution / 溶出度	at least 75% (Q) after 45min 45分钟后至少75% (Q)	90. %
<u>Identification / 鉴别</u>		
Brivudine / 溴夫定	Comparison with reference substance (HPLC, UV absorption spectrophotometry) / 与对照品对比 (HPLC, UV吸收分光光度法)	positive 阳性
<u>Purity testing / 纯度检验</u>		
Chemical impurities* / 化学杂质*		
BVU	not more than 0.1 % / 不超过 0.1%	< 0.05 %
$\beta$ -(Z)-BVDU	not more than 0.1 % / 不超过 0.1%	< 0.05 %
BVDU-dimer / BVDU-二聚物	not more than 0.1 % / 不超过 0.1%	< 0.05 %
Unknown impurity (RRT = 1.55) / 未知杂质(RRT=1.55)	not more than 0.1 % / 不超过 0.1%	< 0.05 %
Each of unknown impurities / 每个其他未知杂质	not more than 0.1 % / 不超过 0.1%	< 0.05 %
Sum of unknown impurities / 未知杂质总和	not more than 0.5 % / 不超过 0.5%	< 0.1 %
$\alpha$ -(E)-BVDU	not more than 0.1 % / 不超过 0.1%	< 0.1 %
Sum of all impurities / 所有杂质总和	not more than 1.0 % / 不超过 1.0 %	< 0.1 %
Microbial contamination / 微生物污染		
TAMC	not more than 10 <sup>3</sup> CFU/g 不超过10 <sup>3</sup> CFU/g	< 100. CFU/g
TYMC	not more than 10 <sup>2</sup> CFU/g 不超过10 <sup>2</sup> CFU/g	< 10. CFU/g
Escherichia coli / 大肠埃希菌	absent in 1 g / 1g 中未检出	conforms / 符合
<u>Assay / 含量测定</u>		
Brivudine / 溴夫定	118.75 to 131.25 mg /tablet 118.75 - 131.25 mg/片	124.22 mg

\* Test frequency: every 10<sup>th</sup> batch / \*检验频率: 每10个批次

### Certificate / 认证:

The batch complies with the agreed specification and has been released by a Qualified Person.

Zostex ® meets the requirements of China imported drug registered Specification JX20190268.

该批次符合质量标准的要求, 并经质量授权人放行。

溴夫定片符合中国进口注册标准JX20190268的要求。

Dr. Norbert Stang

Qualified Person / 质量授权人  
02/02/2024







# BERLIN-CHEMIE MENARINI

## Analysenzertifikat

## Certificate of Analysis

## Сертификат анализа

Product / 产品:  
MENARINI Code no. / MENARINI 代码编号:  
BC Code no. / BC代码编号:  
Batch no. / 批号: 33502A  
Date of Manufacture / 生产日期: 10/2023  
Date of Batch Release / 批放行日期: 08/12/2023

检验报告  
Zostex ® / 溴夫定片  
RBINVZTXCN2004  
F146229

Date of Expiry / 有效期: 09/2026

### Item / 项目 Appearance / 性状

Specification / 质量标准  
White or off-white tablets  
白色或类白色片  
245 mg  $\pm$  5 %

Result / 结果  
conforms  
符合  
243. mg

### Average mass / 平均质量 Testing of the dosage form 剂型的检验

Uniformity of dosage units /  
剂量单位的均匀度

Complies with Ph.Eur. 2.9.40 by mass variation /  
符合欧洲药典的要求2.9.40 质量差异  
not more than 1 %  
不超过1 %

conforms  
符合  
< 1. %

Friability / 脆碎度

Dissolution / 溶出度

at least 75% (Q) after 45min  
45分钟后至少75% (Q)

81. %

### Identification / 鉴别

Brivudine / 溴夫定

Comparison with reference substance  
(HPLC, UV absorption spectrophotometry) /  
与对照品对比 (HPLC, UV吸收分光光度法)

positive  
阳性

### Purity testing / 纯度检验

#### Chemical impurities\* / 化学杂质\*

BVU  
 $\beta$ -(Z)-BVDU  
BVDU-dimer / BVDU-二聚物  
Unknown impurity (RRT = 1.55) /  
未知杂质(RRT=1.55)  
Each of unknown impurities /  
每个其他未知杂质  
Sum of unknown impurities /  
未知杂质总和  
 $\alpha$ -(E)-BVDU  
Sum of all impurities / 所有杂质总和

not more than 0.1 % / 不超过 0.1 %  
not more than 0.1 % / 不超过 0.1 %  
not more than 0.1 % / 不超过 0.1 %  
not more than 0.1 % / 不超过 0.1 %  
not more than 0.1 % / 不超过 0.1 %  
not more than 0.5 % / 不超过 0.5 %  
not more than 0.1 % / 不超过 0.1 %  
not more than 1.0 % / 不超过 1.0 %

not tested / 未检测  
not tested / 未检测  
not tested / 未检测  
not tested / 未检测  
not tested / 未检测  
not tested / 未检测  
not tested / 未检测  
not tested / 未检测

#### Microbial contamination / 微生物污染

TAMC

not more than  $10^3$  CFU/g  
不超过  $10^3$  CFU/g

< 100. CFU/g

TYMC

not more than  $10^2$  CFU/g  
不超过  $10^2$  CFU/g

< 10. CFU/g

Escherichia coli / 大肠埃希菌

absent in 1 g / 1g 中未检出

conforms / 符合

### Assay / 含量测定

Brivudine / 溴夫定

118.75 to 131.25 mg / tablet  
118.75 - 131.25 mg / 片

122.96 mg

\* Test frequency: every  $10^{\text{th}}$  batch / \*检验频率: 每10个批次

### Certificate / 认证:

The batch complies with the agreed specification and has been released by a Qualified Person.

Zostex ® meets the requirements of China imported drug registered Specification JX20190268.

该批次符合质量标准的要求, 并经质量授权人放行。

溴夫定片符合中国进口注册标准JX20190268的要求。

Dr. Norbert Stang

Qualified Person / 质量授权人  
08/12/2023





**BERLIN-CHEMIE  
MENARINI**

检验报告

**Analysenzertifikat**

**Certificate of Analysis**

**Сертификат анализа**

Product/产品: **Espumisan® / 西甲硅油乳剂**  
MENARINI Code no./ 代码编号: **RBINVESPCN2005**  
BC Code no./ 代码编号: **F152420**  
Batch no./ 批号: **34072A**  
Date of Manufacture/生产日期: **12/2023**  
Date of Batch Release/批放行日期: **23/01/2024**

Date of Expiry/有效期: **11/2026**

<u>Item / 项目</u>	<u>Specification / 质量标准</u>	<u>Result / 结果</u>
Appearance/ 外观	milky-white, low-viscous emulsion/ 乳白色, 低黏度乳剂	conforms/符合
Odour/ 气味	fruity of banana/ 香蕉果味	conforms/符合
Mean filling quantity/ 平均灌装量	NLT 30 ml	30 ml
Minus deviation / 负偏差	NMT 2.7 ml	conforms/符合
Dose and uniformity of dose of oral drops/ 口服滴剂剂量和剂量均匀度*	No single mass deviates by more than $\pm 10\%$ from the average mass of 10 doses. The total of 10 masses does not differ by more than $\pm 15\%$ from the nominal mass of 10 doses. / 单个质量与10个剂量的平均质量偏差不得过 $\pm 10\%$ . 10个剂量的总和, 与10个剂量的标称质量相差未超过 $\pm 15\%$ .	not tested/ 未检测
Dropping speed/ 滴出速度	NMT 2 drops per second/ NMT 每秒2滴	conforms/符合
Emulsion stability/ 乳剂稳定性	no phase separation at centrifugation/ 离心分离时不分相	conforms/符合
Dynamic viscosity/ 动态黏度	90 to 150 mPa·s	106 mPa·s
Relative density/ 相对密度	1.060 $\pm$ 0.020	1.060
Defoaming capability/ 消泡能力	NLT 80 %	100. %
pH	4.8 to 5.2	5.0
<u>Identification / 鉴别</u>		
Polydimethylsiloxane (PDMS)/ 聚二甲基硅氧烷	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Silica / 二氧化硅 *	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Sorbic acid / 山梨酸	Comparison with reference substance (HPLC)/ 与标准品对比 (HPLC)	positive/ 阳性
<u>Microbial impurity / 微生物杂质 *</u>		
TAMC / 总需氧菌数	NMT 10 <sup>2</sup> CFU/ ml	not tested/未检测
TYMC / 霉菌和酵母菌总数	NMT 10 <sup>1</sup> CFU/ ml	not tested/未检测
Escherichia coli/ 大肠埃希菌	absent in 1 ml / 1ml中未检出	not tested/未检测
<u>Assay / 含量测定</u>		
Simeticone total composed of PDMS : silica = 96:4 / 西甲硅油由 PDMS:二氧化硅=96:4*构成	37.0 to 43.0 mg/ml	41.2 mg/ml
PDMS / 聚二甲基硅氧烷	95 to 105% of the theoretical content of 38.4 mg/ml / 38.4mg/ml的理论含量的95-105%	101 %
Silica / 二氧化硅 *	maximum 2.7 mg/ml / 最大值2.7mg/ml	2.3 mg/ml
Sorbic acid / 山梨酸	90 to 110% of the declared content/ 标示含量的90-110%	101 %

\* Test is performed on every 10<sup>th</sup> batch, at least once per year / 该检查每隔10个批次实施, 但至少每年1次。

**Certificate / 证书:**

The batch complies with the agreed specification and has been released by a Qualified Person.

Espumisan® 30ml /bottle meets the requirements of China imported drug registered Specification JX20140233

该批次符合质量标准要求, 并经质量授权人放行。

西甲硅油乳剂 30ml/瓶符合中国进口药品注册标准JX20140233的要求。

**Dr. Norbert Stang**

Qualified Person/ 质量授权人  
23/01/2024



Vorsitzender des Aufsichtsrates: Dr. Alberto Giovanni Aleotti · Vorstand: Dr. Luca Lastrucci (Vorsitzender), Edward Szybowski, Dr. Christian Matschke, Dr. Attilio Sebastio, Christiane von der Eltz, Ivan Bergstein · Postanschrift: BERLIN-CHEMIE AG, 12485 Berlin · Tel. +49 30 6707-0 (Zentrale), Fax +49 30 6707-2008 (Qualitätskontrolle).



检验报告

**Analysenzertifikat**

**Certificate of Analysis**

**Сертификат анализа**

Product/产品: **Espumisan® / 西甲硅油乳剂**  
MENARINI Code no./ 代码编号: **RBINVESPCN2005**  
BC Code no./ 代码编号: **F152420**  
Batch no./ 批号: **34073A**  
Date of Manufacture/生产日期: **12/2023**  
Date of Batch Release/批放行日期: **19/01/2024**

Date of Expiry/有效期: **11/2026**

<b>Item / 项目</b>	<b>Specification / 质量标准</b>	<b>Result / 结果</b>
Appearance/ 外观	milky-white, low-viscous emulsion/ 乳白色, 低黏度乳剂	conforms/符合
Odour/ 气味	fruity of banana/ 香蕉果味	conforms/符合
Mean filling quantity/ 平均灌装量	NLT 30 ml	30 ml
Minus deviation / 负偏差	NMT 2.7 ml	conforms/符合
Dose and uniformity of dose of oral drops/ 口服滴剂剂量和剂量均匀度*	No single mass deviates by more than $\pm 10\%$ from the average mass of 10 doses. The total of 10 masses does not differ by more than $\pm 15\%$ from the nominal mass of 10 doses. / 单个质量与10个剂量的平均质量偏差不得超过 $\pm 10\%$ . 10个剂量的总和, 与10个剂量的标称质量相差未超过 $\pm 15\%$ .	conforms/符合
Dropping speed/ 滴出速度	NMT 2 drops per second/ NMT 每秒2滴	conforms/符合
Emulsion stability/ 乳剂稳定性	no phase separation at centrifugation/ 离心分离时不分相	conforms/符合
Dynamic viscosity/ 动态黏度	90 to 150 mPa·s	105 mPa·s
Relative density/ 相对密度	1.060 $\pm$ 0.020	1.060
Defoaming capability/ 消泡能力	NLT 80 %	100. %
pH	4.8 to 5.2	5.0
<b>Identification / 鉴别</b>		
Polydimethylsiloxane (PDMS)/ 聚二甲基硅氧烷	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Silica / 二氧化硅 *	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Sorbic acid / 山梨酸	Comparison with reference substance (HPLC)/ 与标准品对比 (HPLC)	positive/ 阳性
<b>Microbial impurity / 微生物杂质 *</b>		
TAMC / 总需氧菌数	NMT 10 <sup>2</sup> CFU/ ml	< 1. CFU/ml
TYMC / 霉菌和酵母菌总数	NMT 10 <sup>1</sup> CFU/ ml	< 1. CFU/ml
Escherichia coli/ 大肠埃希菌	absent in 1 ml / 1ml中未检出	conforms/符合
<b>Assay / 含量测定</b>		
Simeticone total composed of PDMS : silica = 96.4 / 西甲硅油由PDMS:二氧化硅=96.4*构成	37.0 to 43.0 mg/ml	41.5 mg/ml
PDMS / 聚二甲基硅氧烷	95 to 105% of the theoretical content of 38.4 mg/ml / 38.4mg/ml的理论含量的95-105%	102 %
Silica / 二氧化硅 *	maximum 2.7 mg/ml / 最大值2.7mg/ml	2.4 mg/ml
Sorbic acid / 山梨酸	90 to 110% of the declared content/ 标示含量的90-110%	101 %

\* Test is performed on every 10<sup>th</sup> batch, at least once per year / 该检查每隔10个批次实施, 但至少每年1次。

**Certificate / 证书:**

The batch complies with the agreed specification and has been released by a Qualified Person.

Espumisan® 30ml /bottle meets the requirements of China imported drug registered Specification JX20140233

该批次符合质量标准要求, 并经质量授权人放行。

西甲硅油乳剂 30ml/瓶符合中国进口药品注册标准JX20140233的要求。

**Dr. Norbert Stang**  
Qualified Person/ 质量授权人  
19/01/2024







检验报告

**Analysenzertifikat**

**Certificate of Analysis**

**Сертификат анализа**

Product/产品: **Espumisan® / 西甲硅油乳剂**  
MENARINI Code no./ 代码编号: **RBINVESPCN2005**  
BC Code no./ 代码编号: **F152420**  
Batch no./ 批号: **34074A**  
Date of Manufacture/生产日期: **12/2023**  
Date of Batch Release/批放行日期: **19/01/2024**

Date of Expiry/有效期: **11/2026**

<u>Item / 项目</u>	<u>Specification / 质量标准</u>	<u>Result / 结果</u>
Appearance/ 外观	milky-white, low-viscous emulsion/ 乳白色, 低黏度乳剂	conforms/符合
Odour/ 气味	fruity of banana/ 香蕉果味	conforms/符合
Mean filling quantity/ 平均灌装量	NLT 30 ml	30 ml
Minus deviation / 负偏差	NMT 2.7 ml	conforms/符合
Dose and uniformity of dose of oral drops/ 口服滴剂剂量和剂量均匀度*	No single mass deviates by more than $\pm 10\%$ from the average mass of 10 doses. The total of 10 masses does not differ by more than $\pm 15\%$ from the nominal mass of 10 doses. / 单个质量与10个剂量的平均质量偏差不得过 $\pm 10\%$ . 10个剂量的总和与10个剂量的标称质量相差未超过 $\pm 15\%$ .	not tested/未检测
Dropping speed/ 滴出速度	NMT 2 drops per second/ NMT 每秒2滴	conforms/符合
Emulsion stability/ 乳剂稳定性	no phase separation at centrifugation/ 离心分离时不分相	conforms/符合
Dynamic viscosity/ 动态黏度	90 to 150 mPa·s	107 mPa·s
Relative density/ 相对密度	1.060 $\pm$ 0.020	1.060
Defoaming capability/ 消泡能力	NLT 80 %	100. %
pH	4.8 to 5.2	5.0
<u>Identification / 鉴别</u>		
Polydimethylsiloxane (PDMS)/ 聚二甲基硅氧烷	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Silica / 二氧化硅 *	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Sorbic acid / 山梨酸	Comparison with reference substance (HPLC)/ 与标准品对比 (HPLC)	positive/ 阳性
<u>Microbial impurity / 微生物杂质 *</u>		
TAMC / 总需氧菌数	NMT $10^2$ CFU/ ml	not tested/未检测
TYMC / 霉菌和酵母菌总数	NMT $10^1$ CFU/ ml	not tested/未检测
Escherichia coli/ 大肠埃希菌	absent in 1 ml / 1ml中未检出	not tested/未检测
<u>Assay / 含量测定</u>		
Simeticone total composed of PDMS : silica = 96:4 / 西甲硅油由 PDMS:二氧化硅=96:4*构成	37.0 to 43.0 mg/ml	41.7 mg/ml
PDMS / 聚二甲基硅氧烷	95 to 105% of the theoretical content of 38.4 mg/ml / 38.4mg/ml的理论含量的95-105%	103 %
Silica / 二氧化硅 *	maximum 2.7 mg/ml / 最大值2.7mg/ml	2.4 mg/ml
Sorbic acid / 山梨酸	90 to 110% of the declared content/ 标示含量的90-110%	101 %

\* Test is performed on every 10<sup>th</sup> batch, at least once per year / 该检查每隔10个批次实施,但至少每年1次。

**Certificate / 证书:**

The batch complies with the agreed specification and has been released by a Qualified Person.

Espumisan® 30ml /bottle meets the requirements of China imported drug registered Specification JX20140233

该批次符合质量标准要求,并经质量授权人放行。

西甲硅油乳剂 30ml/瓶符合中国进口药品注册标准JX20140233的要求。

**Dr. Norbert Stang**

Qualified Person/ 质量授权人  
19/01/2024





检验报告

**Analysenzertifikat**

**Certificate of Analysis**

**Сертификат анализа**

Product/产品: **Espumisan® / 西甲硅油乳剂**  
MENARINI Code no./ 代码编号: **RBINVESPCN2005**  
BC Code no./ 代码编号: **F152420**  
Batch no./ 批号: **34075A**  
Date of Manufacture/生产日期: **12/2023**  
Date of Batch Release/批放行日期: **26/01/2024**

Date of Expiry/有效期: **11/2026**

<u>Item / 项目</u>	<u>Specification / 质量标准</u>	<u>Result / 结果</u>
Appearance/ 外观	milky-white, low-viscous emulsion/ 乳白色, 低黏度乳剂	conforms/符合
Odour/ 气味	fruity of banana/ 香蕉果味	conforms/符合
Mean filling quantity/ 平均灌装量	NLT 30 ml	30 ml
Minus deviation / 负偏差	NMT 2.7 ml	conforms/符合
Dose and uniformity of dose of oral drops/ 口服滴剂剂量和剂量均匀度*	No single mass deviates by more than $\pm 10\%$ from the average mass of 10 doses. The total of 10 masses does not differ by more than $\pm 15\%$ from the nominal mass of 10 doses. / 单个质量与10个剂量的平均质量偏差不得超过 $\pm 10\%$ . 10个剂量的总和, 与10个剂量的标称质量相差未超过 $\pm 15\%$ .	not tested/未检测
Dropping speed/ 滴出速度	NMT 2 drops per second/ NMT 每秒2滴	conforms/符合
Emulsion stability/ 乳剂稳定性	no phase separation at centrifugation/ 离心分离时不分相	conforms/符合
Dynamic viscosity/ 动态黏度	90 to 150 mPa·s	105 mPa·s
Relative density/ 相对密度	1.060 $\pm$ 0.020	1.060
Defoaming capability/ 消泡能力	NLT 80 %	100. %
pH	4.8 to 5.2	5.0
<u>Identification / 鉴别</u>		
Polydimethylsiloxane (PDMS)/ 聚二甲基硅氧烷	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Silica / 二氧化硅 *	Comparison with reference substance (IR)/ 与标准品对比 (IR)	positive/ 阳性
Sorbic acid / 山梨酸	Comparison with reference substance (HPLC)/ 与标准品对比 (HPLC)	positive/ 阳性
<u>Microbial impurity / 微生物杂质 *</u>		
TAMC / 总需氧菌数	NMT $10^2$ CFU/ ml	not tested/未检测
TYMC / 霉菌和酵母菌总数	NMT $10^1$ CFU/ ml	not tested/未检测
Escherichia coli/ 大肠埃希菌	absent in 1 ml / 1ml中未检出	not tested/未检测
<u>Assay / 含量测定</u>		
Simeticone total composed of PDMS : silica = 96:4 / 西甲硅油由 PDMS:二氧化硅=96.4*构成	37.0 to 43.0 mg/ml	41.7 mg/ml
PDMS / 聚二甲基硅氧烷	95 to 105% of the theoretical content of 38.4 mg/ml / 38.4mg/ml的理论含量的95-105%	103 %
Silica / 二氧化硅 *	maximum 2.7 mg/ml / 最大值2.7mg/ml	2.4 mg/ml
Sorbic acid / 山梨酸	90 to 110% of the declared content/ 标示含量的90-110%	99 %

\* Test is performed on every 10<sup>th</sup> batch, at least once per year / 该检查每隔10个批次实施, 但至少每年1次。

**Certificate / 证书:**

The batch complies with the agreed specification and has been released by a Qualified Person.

Espumisan® 30ml /bottle meets the requirements of China imported drug registered Specification JX20140233

该批次符合质量标准要求, 并经质量受权人放行。

西甲硅油乳剂 30ml /瓶符合中国进口药品注册标准JX20140233的要求。

**Dr. Norbert Stang**

Qualified Person/ 质量受权人  
26/01/2024




Original



ace europe

ACE European Group Limited  
Direktion für Deutschland Lurgallee 12, 60439 Frankfurt, Deutschland  
Tel +49 69 7 56 13-0 Fax +49 69 74 61 93

Direktion für Deutschland eingetragen HRB Frankfurt 58029 .  
Hauptbevollmächtigter: Andreas Wanla . USt-Id-Nr. DE 240 196 168 Hauptsitz der Gesellschaft: London, United Kingdom , GmbH nach englischem Recht  
ACE European Group Limited unterliegt der Zulassung und Regulierung der Prudential Regulation Authority, 20 Moorgate, London EC2R 6DA, UK, sowie in Deutschland zusätzlich den Regularien der Bundesanstalt für Finanzdienstleistungsaufsicht (BaFin) zur Ausübung der Geschäftstätigkeit, welche sich von den Regularien des Vereinigten Königreichs (UK) unterscheiden können.

<b>MARINE INSURANCE CERTIFICATE</b>		N° BC013971	
Assured: Berlin-Chemie AG Glienicke Weg 125 12489 Berlin / Germany		Policy No: 010550284D	Date: 01.03.2024 Exporter Ref:
Description of the cargo <i>Nature and number of packages / Marks</i>  Purchase order no.: 1-006417, 1-006189, 1-006110 Pharmaceuticals packed on 4x40'cont cont.1(pl.1-23,40'), cont.2(pl.24-46 cont.3(pl.47-69,40')cont.4(pl.70-92 (according to packing list no: K002974755)  Marks, numbers and weight gross weight 28288,28 kgs net weight 25894,02 kgs		Voyage: <i>From</i>  by seafreight from Hamburg/ Ger  <i>To</i> to Shanghai / China  Steamer and/or other conveyances:	
In case of loss or damages apply for survey to:  ACE International Insurance Co of Hong Kong 25F, Shui On Centre No 6-8 Harbour Road Wanchai, Hong Kong Tel: +852 3191 8800		Claims to be settled by: ACE Europe Insurance	
Insured Value: EUR 375783,32	In words: EUR three hundred seventy five thousand seven hundred eighty three 32/100		
General Conditions: Terms and Conditions of the above Open Policy.			
Specific Conditions			
Signature of Insurers: ACE European Group Limited  		Place and date of issue: Berlin, 01.03.2024  Not transferable unless counter signed	
All indemnity for loss or damage will be paid, in accordance with the conditions of the General policy to the holder of the original insurance Certificate and the substantiating claim documents			

Issued in 1 original(s), 1 duplicate(s), 2 copies



## WHAT TO DO IN THE EVENT OF LOSS OR DAMAGE?

IMMEDIATE ACTION is required in the event that a shipment arrives damaged or incomplete!

### UPON RECEIVING CARGO:

1. Examine all packages for external damage and count number. Note any signs of damage and/or shortage on the (CMR) Waybill, Bill of Lading, Airway Bill and/or Delivery Receipt before you accept delivery!
2. If the shipment contains fragile items, or if the Tipp & Tell unit is triggered, open the packages to check for breakage/damage, even if there is no visible external damage.
3. Always open packages within 3 days of delivery. If there is „concealed damage“, hold the delivering carrier responsible (see point 3° in the following section).

### IF THERE IS DAMAGE OR LOSS:

1. Take photographs of any damaged goods/packages, if possible and do not discard (damaged) packing materials or contents.
2. Make every effort to minimize the loss and prevent further loss.
3. Immediately hold the carrier(s) responsible in writing for any ‚visible‘ loss not noted on the Delivery Receipt or ‚concealed‘ loss or damage, respecting the following delays:  
For Ocean Carriage : within 3 days of delivery;  
For Trucking, Railways and Air shipments : within 7 days of delivery.  
Include in this letter/fax or e-mail an invitation to attend a joint survey, quoting the B/L-, Air-, (CMR) Waybill- or Delivery Receipt number(s), whatever the case may be. A brief description of the loss or damage should be included with note that a final claim will follow when the full extent of loss/damage has been established.

### IMPORTANT:

If the claim is expected to be above € 2.000, - (net of deductible), immediately notify the nearest ACE office- or ACE appointed Average Agent mentioned on the face of / in the Insurance Certificate. In the absence of any such office or agents, the nearest Lloyd's agent may be asked to arrange for a survey of the shipment, which is to be carried out jointly with carrier(s).

### REQUIRED DOCUMENTS TO SUPPORT A MARINE CARGO CLAIM:

The following list of documents is intended to cover most situations, however each claim is unique and additional documents may be required

- Original Insurance Certificate and endorsements, if any
- Formal claim, including salvage- / repair- and/or replacement invoices
- Proof of Delivery (POD) or Delivery Receipt with remarks regarding loss or damage
- Original ocean B/L and/or AWB and/or (CMR/CIM) Waybill
- Shipper's Invoice(s) covering the entire consignment + Packing Lists
- Survey Report
- Copy of Notice of Loss/Invitation to attend Survey to carrier and carrier's reply, if any
- Carrier's confirmation of short- or non delivery
- Equipment Interchange Receipts for containerised shipments, if applicable
- Export/Import declarations, if applicable
- Mate/Dock Receipts at time of loading/discharge and/or Statement of Facts and/or Outturn Report
- Weight Certificates, if applicable

### GENERAL AVERAGE

- In the event General Average is declared, security requirements should be forwarded to the ACE office mentioned on the face of the Insurance Certificate for consideration  
Failure to comply with these instructions may prejudice your claim under the policy