

<p>Project No.: STRESS-L/266-18-042</p> <p>Protocol No.: STRESS-L Trial</p> <p>Product Name: Stress-L Landiolol pat kits 20</p> <p>BPR No. 0079 (BPR 002)</p> <p>Version: 01</p>
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BATCH PACKAGING RECORD No. 0079
(Herstellungsanweisung/Herstellungsprotokoll)



Product Name: CEMS ITEM CODE Substance (Inhaltsstoff): Dosage form (Darreichungsform): Country and/or language (Land und/oder Sprache): Tracking No. (= Batch No.):	Stress-L- Landiolol pat kits 20 0016210 Landiolol hydrochloride 300 mg lyophilised powder Lyo vials with 300 mg all study countries 0079																																				
Batch size (Chargengröße): 130 patient kits, each containing 20 vials Expiry Date (Verfalldatum): 11/2021 Labelled Lot (etikettierte Ch.-B.): 0079																																					
Retention sample (Rückstellmuster): <input type="checkbox"/> Full kit (Vollständiges Kit) <input type="checkbox"/> Reduced kit (Kit mit reduziertem Inhalt): <input checked="" type="checkbox"/> Photo: Final kit (fertiges Kit) <input checked="" type="checkbox"/> Photo: open kit with content (noch geöffnetes Kit mit Inhalt) Print photos and attach to BPR (Photos drucken und dem BPR anhängen)																																					
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:40%;">Approvals</th> <th style="width:20%;">Name</th> <th style="width:20%;">Signature</th> <th style="width:20%;">Date</th> </tr> <tr> <td>BPR reviewed by (geprüft von) QA:</td> <td>A. Megger</td> <td>[Signature]</td> <td>05 / Apr / 2019</td> </tr> <tr> <td>BPR approved by "Leiter Herstellung" (BPR genehmigt durch LH):</td> <td>KLAUS HOFSTÄEDTER</td> <td>[Signature]</td> <td>03 / Apr / 2019</td> </tr> <tr> <td>BPR approved by SPONSOR (BPR genehmigt vom Sponsor):</td> <td>OP</td> <td>[Signature]</td> <td>09 / APR / 2019</td> </tr> <tr> <td>Final Approval by CSM Europe (Final genehmigt durch CSM Europe)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Leiter Herstellung:</td> <td>A. Schneider-Haake</td> <td>[Signature]</td> <td>23 / Apr / 2019</td> </tr> <tr> <td>QA:</td> <td>A. Megger</td> <td>[Signature]</td> <td>24 / Apr / 2019</td> </tr> <tr> <td>Qualified Person:</td> <td>[Signature]</td> <td>[Signature]</td> <td>24 / April / 2019</td> </tr> <tr> <td>Final Approval by Sponsor:</td> <td>Dr. Klaus Hofstaedter Qualified Person</td> <td>[Signature]</td> <td>25 / APR / 2019</td> </tr> </table>		Approvals	Name	Signature	Date	BPR reviewed by (geprüft von) QA:	A. Megger	[Signature]	05 / Apr / 2019	BPR approved by "Leiter Herstellung" (BPR genehmigt durch LH):	KLAUS HOFSTÄEDTER	[Signature]	03 / Apr / 2019	BPR approved by SPONSOR (BPR genehmigt vom Sponsor):	OP	[Signature]	09 / APR / 2019	Final Approval by CSM Europe (Final genehmigt durch CSM Europe)				Leiter Herstellung:	A. Schneider-Haake	[Signature]	23 / Apr / 2019	QA:	A. Megger	[Signature]	24 / Apr / 2019	Qualified Person:	[Signature]	[Signature]	24 / April / 2019	Final Approval by Sponsor:	Dr. Klaus Hofstaedter Qualified Person	[Signature]	25 / APR / 2019
Approvals	Name	Signature	Date																																		
BPR reviewed by (geprüft von) QA:	A. Megger	[Signature]	05 / Apr / 2019																																		
BPR approved by "Leiter Herstellung" (BPR genehmigt durch LH):	KLAUS HOFSTÄEDTER	[Signature]	03 / Apr / 2019																																		
BPR approved by SPONSOR (BPR genehmigt vom Sponsor):	OP	[Signature]	09 / APR / 2019																																		
Final Approval by CSM Europe (Final genehmigt durch CSM Europe)																																					
Leiter Herstellung:	A. Schneider-Haake	[Signature]	23 / Apr / 2019																																		
QA:	A. Megger	[Signature]	24 / Apr / 2019																																		
Qualified Person:	[Signature]	[Signature]	24 / April / 2019																																		
Final Approval by Sponsor:	Dr. Klaus Hofstaedter Qualified Person	[Signature]	25 / APR / 2019																																		

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BATCH PACKAGING RECORD No. 0079
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Product Name: Stress-L Landiolol pat kits 20	Charge: 0079	CEMS ITEM CODE: 0016210
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Material List (Materialliste)						
	CEMS ITEM CODE	Description	Tracking No.	Lot No.	Expiry Date	Amount (Menge)
1.	0016081	Landiolol 300 mg Lyo vial - BULK	SSU01190401 12215675	1805	30-Nov-2021	2,600

Material List for packaging material (Materialliste für Packmittel)					
	CEMS ITEM CODE	Description	Tracking No.	Label No.	Amount (Menge)
2.	0014306	Vial labels	SSU0117112014370574	MLP 001 200649	2,600 + 1
3.	0013673	Carton labels	SSU0117120807063094	MLP 002 200650	130 + 1
4.	0016209	Cartons for 20 vials	SSU0119032513565622	n/a	130
5.	0013745	Sealing labels (transparent)	SSU0117091408304038	n/a	130

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BATCH PACKAGING RECORD No. 0079
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TRAINING RECORD (Nachweis der projektspezifischen Schulung)

Training theme (Thema der Schulung):

secondary packaging (Sekundärverpackung)

Safety (Sicherheit),
 Equipment (Maschinen und Geräte),
 Sanitation (Hygienevorschriften),
 Packaging Instruction (Herstellungsanweisung),

Other (Sonstiges)

n/a

Protective Clothing Requirements:
 (Schutzkleidung)

- Hair coverage (Kopfbedeckung):
- Beard cover (Bartschutz):
- Gloves (Handschuhe):
- Lab coat (Schutzkittel):
- Booties (Überschuhe):

necessary
(notwendig)

not necessary
(nicht notwendig)

Attendees
(Teilnehmer)

Signature
(Unterschrift)

Done by
(durchgeführt von):

Time/Date
(Uhrzeit/Datum)

CINZIA NICOSIA

Cinzia Nicosia

HN

15:25 16 APR 2019

Miriam Ebert

M. Ebert

HN

15:25 16 APR 2019

CAROLINE MULLONZI

Carlonzi

HN

08:55 17 APR 2019

Vivrel Munstermann

Munstermann

HN

08:55 17 APR 2019

Julia Ficksel

Ficksel

HN

08:55 18 APR 2019

Linda Rossi

L. Rossi

HN

08:55 18 APR 2019

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18 Apr 2019

ASU

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CSM Clinical Supplies
 Management Europe GmbH

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 STRESS-L/266-18-042

Version: 01
 Date: 27-Mar-2019

BATCH PACKAGING RECORD No. 0079
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PERSONNEL INVOLVED IN RUN (Beteiligtes Personal)			DATE: <u>16 / Apr / 2019</u> (DD/MMM/YYYY)
Full Name (Name in Blockschrift)	Signature (Unterschrift)	Initials (Namenskürzel)	Start/End time (Start/Ende Uhrzeit)
Supervisor: <u>Vujanovic Marko</u>	<u>Vujanovic</u>	<u>Mr</u>	<u>15:25 / 16:10</u>
Packaging Assistants: (Verpackungspersonal):			
1. <u>CINZIA NICOSIA</u>	<u>Cinzia Nicosia</u>	<u>NC</u>	<u>15:25 / 16:10</u>
2. <u>Miriam Echeit</u>	<u>M. Echeit</u>	<u>EM</u>	<u>15:25 / 16:10</u>
3.			
4.			
5.		<u>ASU</u>	
6.			
Room Temperature (Spec: 15 – 25 °C) (Raumtemperatur)			Start: <u>21,7</u> °C End: <u>21,8</u> °C

1) corrected 18-Apr-2019

PERSONNEL INVOLVED IN RUN (Beteiligtes Personal)			DATE: <u>17 / Apr / 2019</u> (DD/MMM/YYYY)
Full Name (Name in Blockschrift)	Signature (Unterschrift)	Initials (Namenskürzel)	Start/End time (Start/Ende Uhrzeit)
Supervisor: <u>Vujanovic Marko</u>	<u>Vujanovic</u>	<u>Mr</u>	<u>08:55 / 09:35</u>
Packaging Assistants: (Verpackungspersonal):			
1. <u>CINZIA NICOSIA</u>	<u>Cinzia Nicosia</u>	<u>NC</u>	<u>08:55 / 09:35</u>
2. <u>LAROLINE MUKONZI</u>	<u>Mukonzi</u>	<u>CM</u>	<u>08:55 / 09:35</u>
3. <u>Violet Munteanu</u>	<u>Munteanu</u>	<u>VM</u>	<u>08:55 / 09:35</u>
4. <u>Hi</u> <small>18 Apr 2019 EM</small>			
5.		<u>ASU</u>	
6.			
Room Temperature (Spec: 15 – 25 °C) (Raumtemperatur)			Start: <u>20,7</u> °C End: <u>20,7</u> °C

2) corrected 18-Apr-2019

Please make sufficient copies of this page for all packaging days (Diese Seite für weitere Verpackungstage kopieren)

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PERSONNEL INVOLVED IN RUN (Beteiligtes Personal)			DATE: <u>18/Apr/2019</u> (DD/MMM/YYYY)
Full Name (Name in Blockschrift)	Signature (Unterschrift)	Initials (Namenskürzel)	Start/End time (Start/Ende Uhrzeit)
Supervisor:			
<u>Vujanović Marko</u>	<u>[Signature]</u>	<u>VM</u>	<u>08:55 / 13:25</u>
Packaging Assistants: (Verpackungspersonal):			
1. <u>Julia Ficksel</u>	<u>Ficksel</u>	<u>JF</u>	<u>08:55 / 13:25</u>
2. <u>Linda Razić</u>	<u>L. Razić</u>	<u>LR</u>	<u>08:55 / 13:25</u>
3. <u>LAROLINE MUKONZI</u>	<u>Mukonzi</u>	<u>CM</u>	<u>08:55 / 13:25</u>
4. <u>CINZIA NICOSIA</u>	<u>Cinzia Nicosia</u>	<u>NC</u>	<u>08:55 / 13:25</u>
5. <u>Miriam Echeit</u>	<u>M. Echeit</u>	<u>EM</u>	<u>08:55 / 13:25</u>
6. <u>N/A 18 Apr 2019 ASu</u>	<u>ASu</u>		<u>— : — / — : —</u>
Room Temperature (Spec: 15 – 25 °C) (Raumtemperatur)		Start: <u>21.1</u> °C	End: <u>21.1</u> °C

PERSONNEL INVOLVED IN RUN (Beteiligtes Personal)			DATE: <u>— / — / 20—</u> (DD/MMM/YYYY)
Full Name (Name in Blockschrift)	Signature (Unterschrift)	Initials (Namenskürzel)	Start/End time (Start/Ende Uhrzeit)
Supervisor:			
.....	<u>— : — / — : —</u>
Packaging Assistants: (Verpackungspersonal):			
1. <u>N/A 18 Apr 2019 ASu</u>			<u>— : — / — : —</u>
2.			<u>— : — / — : —</u>
3.			<u>— : — / — : —</u>
4.			<u>— : — / — : —</u>
5.			<u>— : — / — : —</u>
6.			<u>— : — / — : —</u>
Room Temperature (Spec: 15 – 25 °C) (Raumtemperatur)		Start: °C	End: °C

Please make sufficient copies of this page for all packaging days (Diese Seite für weitere Verpackungstage kopieren)

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BATCH PACKAGING RECORD No. 0079
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PACKAGING INSTRUCTIONS (Verpackungsanweisung)		
Procedure (Ablauf)	Date/Initials 1	Date/Initials 2
1. Date/time started: <u>16 / Apr / 2019</u> <u>15:25</u> Packaging Room No: <u>3</u> Room clearance/Line clearance: Check of Packaging Room (PR) for cleanliness and absence of other materials and waste. Room log to be completed.	16 APR 2019 <i>dr</i>	16 APR 2019 <i>NC</i>
2. Bring Landiolol Lyo vials tracking No.: SSU0119040112215675/item code 0016081 into the packaging room (= 2,600 vials) and store them in the cooling chamber of the packaging area.	16 APR 2019 <i>dr</i>	16 APR 2019 <i>NC</i>
3. Check lot: 1805	16 APR 2019 <i>dr</i>	16 APR 2019 <i>NC</i>
4. Bring cartons SSU0119032513565622 for 20 vials each into the packaging room.	16 APR 2019 <i>dr</i>	16 APR 2019 <i>NC</i>
5. Bring carton labels SSU into the packaging room. <i>SSU 0117120807063054 12 APR 2019 JE</i> EudraCT Number: 2017-001785-14 FOR CLINICAL TRIAL USE ONLY Protocol: STRESS-L Trial 20 vials x Landiolol hydrochloride 300 mg lyophilised powder for solution for intravenous injection and infusion For use in the STRESS-L Trial ONLY Store at +2°C to +8°C Batch/Lot No.: 0079 Expiry: 11/2021 PI: _____ Site Name/No.: _____ Sponsor: University Hospitals Birmingham NHS Foundation Trust, Edgbaston, Birmingham, B15 2GW Tel: +44 (0) 121 371 4185 Chief Investigator: Dr Tony Whitehouse	17 APR 2019 <i>dr</i>	17 APR 2019 <i>NC</i>
6. Label all cartons (= 130) with the corresponding labels on top of carton.	17 APR 2019 <i>dr</i>	17 APR 2019 <i>NC</i>
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PACKAGING INSTRUCTIONS (Verpackungsanweisung)		
Procedure (Ablauf)	Date/Initials 1	Date/Initials 2
<p>7. <u>Line clearance:</u></p> <p>Remove all remaining cartons and carton labels from the packaging room.</p> <p><u>Check room regarding the following remaining items and remove:</u></p> <p><input checked="" type="checkbox"/> Cartons/Boxes <input checked="" type="checkbox"/> Labels <input type="checkbox"/> Educt <input type="checkbox"/> Product <input type="checkbox"/> Supplies <input type="checkbox"/> Other Materials _____</p>	17 APR 2019 <i>HW</i>	17 APR 2019 <i>NC</i>
<p>8. Take 200 blank Landiolol Lyo vials tracking No.: SSU0119040112215675/item code 0016081 out of the cooling chamber.</p>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
<p>9. Check lot: 1805</p>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
<p>10. Bring vial labels SSU0117112014370574 into the packaging room.</p> <p>EudraCT Number: 2017-001785-14</p> <p>FOR CLINICAL TRIAL USE ONLY Protocol: STRESS-L Trial 1 vial x Landiolol hydrochloride 300 mg lyophilised powder for solution for intravenous injection and infusion For use in the STRESS-L Trial ONLY Store at +2°C to +8°C Batch/Lot No.: 0079 Expiry: 11/2021 Patient Trial ID: _____</p> <p>Sponsor: University Hospitals Birmingham NHS Foundation Trust</p>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
<p>11. Label 200 Landiolol Lyo vials with corresponding label on each vial.</p>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
<p>12. Take a photo of a labelled vial.</p>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
<p>13. Put 20 vials each into the carton according to photo:</p> 	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
<p>CSM Clinical Supplies Management Europe GmbH</p>	<p>Project No. STRESS-L/266-18-042</p>	<p>Version: 01 Date: 27-Mar-2019</p>

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PACKAGING INSTRUCTIONS (Verpackungsanweisung)			
Procedure (Ablauf)		Date/Initials 1	Date/Initials 2
14.	IPC: Check whether all vials are labelled and whether all cartons contain 20 vials.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
15.	Take a photo of the open carton with 20 vials.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
16.	Bring sealing labels SSU0117091408304038/item code 0013745 into the packaging room.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
17.	Close cartons and seal with sealing label.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
18.	Take a photo of the closed and sealed carton.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
19.	Store all kits with labelled vials in the cooling chamber of the packaging room.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
20.	Repeat steps 8, 9, 11, 13, 14, 17 and 19 until all vials (= 2,600) are labelled and put into cartons.	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
21.	<p><u>Room clearance:</u></p> <p>Remove all materials according to the Material List from the packaging area.</p> <p><u>Check room regarding the following remaining items and remove all:</u></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Cartons/Boxes <input checked="" type="checkbox"/> Labels <input checked="" type="checkbox"/> Educt <input checked="" type="checkbox"/> Product <input type="checkbox"/> Supplies <input checked="" type="checkbox"/> Tamper Evident Seals <input type="checkbox"/> Other Materials _____ <input checked="" type="checkbox"/> Waste <p>Clean PR: <u>3</u></p> <p>Room log to be completed.</p> <p>Move finished/labelled product to the appropriate storage area.</p>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>
22.	Time completed: <u>13</u> : <u>25</u>	18 APR 2019 <i>HW</i>	18 APR 2019 <i>NC</i>

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PACKAGING INSTRUCTIONS (Verpackungsanweisung)		
Procedure (Ablauf)	Date/Initials 1	Date/Initials 2
23.	Final inspection by Leiter Qualitätskontrolle (LQK):	
	<p style="text-align: right;"> 23. Apr 2019 A. Pol Date/Signature </p>	

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No	Deviations (Abweichungen)	Date/ Signature	QP review Sign/Date
1	<p>Description (Beschreibung): <i>During packaging run, packaging assistants noticed residues of unknown substance on outside of 2 vials and in addition a slightly damaged vial</i></p> <p>Root Cause (Hauptursache): <i>damaged vial</i> <i>To be clarified with sponsor / vendor of IMP</i></p> <p>Risk Assessment (Risikobewertung): <i>Low, as all affected vials were rejected and not used for packaging</i></p> <p>Corrective Action (Korrekturmaßnahmen): <i>3 vials were rejected during packaging and exchanged with 3 vials from the same batch to fulfil packaging quantity of 130 kits</i> <i>3 rejected at 23 Apr 2019 DM vials were re-entered into ERP system under status on hold until further clarification with sponsor</i></p>	<p><i>23 Apr 2019</i> <i>DM</i></p>	<p><i>[Signature]</i> <i>24 Apr 2019</i></p>
	<p>Description (Beschreibung):</p> <p>Root Cause (Hauptursache):</p> <p>Risk Assessment (Risikobewertung):</p> <p>Corrective Action (Korrekturmaßnahmen):</p> <p><i>PIA 23 Apr 2019 DM</i></p>		
	<p>Description (Beschreibung):</p> <p>Root Cause (Hauptursache):</p> <p>Risk Assessment (Risikobewertung):</p> <p>Corrective Action (Korrekturmaßnahmen):</p>		

Please make copies of this page if more than 3 deviations (Diese Seite kopieren bei mehr als 3 Abweichungen)

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PRODUCT ACCOUNTABILITY (Produktbilanzierung)				
Product Description (Produkt Beschreibung)		Landiolo1 Lyo vials 300 mg		
Batch No. (Chargen-Nr.)		1805 expiry date 11/2021		
Tracking No.		SSU0119040112215675/ 0016081		
A	Starting Quantity (Anfangsmenge)	2600 + 3		
B	Quantity used for study (Für Studie verwendete Menge)	2600		
C	Quantity used for samples (Für Muster benötigte Menge) A = analytical sample R = retention sample	A = 0 R = 0	A R	A R
D	Quantity rejected (Ausschussmenge)	3		
E	Quantity returned unused (nicht verwendete Restmenge)	0		
Accountability (Bilanzierung): B+C+D+E x 100 % A		100%		
If accountability is not 100 %, follow-up in deviation section.				
Completed by (ausgefüllt von): (Date/Sign.)		18 APR 2019 <i>[Signature]</i>		
Checked by (geprüft von): (Date/Sign.)		18 APR 2019 <i>Linie Nicole</i>		

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LABEL ACCOUNTABILITY (Etikettenbilanzierung)					
Label Description (Label Beschreibung)		Carton label Landiolol Lyo 300 mg	vial label Landiolol Lyo 300 mg		
Label specification (Etikettenspezifikation: Typ, Lieferant, x_pro Bogen oder Endlos)		single country label	single country label		
Tracking No.		SSU0117120807063094	SSU0117112014370574		
A	Starting Quantity (Anfangsmenge)	137	2613		
B	Quantity replaced (Ersatz-Etiketten)	0	0		
C	Quantity used for study (Für Studie verwendete Menge)	130	2600		
D	Quantity used for samples (Für Muster benötigte Menge)	0	0		
E	Quantity used for documentation (Für Dokumentation benötigte Menge)	1	1		
F	Quantity remaining unused (Restmenge an ungebrauchten Etiketten)	6	9		
G	Quantity rejected (Ausschussmenge)	0	3		
Accountability (Bilanzierung): $\frac{C+D+E+F+G}{A+B} \times 100 \%$		100%	100%		
If accountability is not 100 %, follow-up in deviation section.					
Remaining labels (Restetiketten):		<input checked="" type="checkbox"/> destroyed (vernichtet) <input type="checkbox"/> returned to stock (zum Bestand zurückgeführt) <input type="checkbox"/> none (keine)			
Completed by (ausgefüllt von): (Date/Sign.)		18 APR 2019 <i>[Signature]</i>	18 APR 2019 <i>[Signature]</i>		
Checked by (geprüft von): (Date/Sign.)		18 APR 2019 <i>[Signature]</i>	18 APR 2019 <i>[Signature]</i>		

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“Herstellung/Verpackung auf Risiko”

CSM Europe wird bei der Wareneingangskontrolle die Bulkware auf Plausibilität prüfen, d.h. es wird eine Sichtkontrolle der Ware durchgeführt und ein Vergleich anhand der Chargendokumentation vorgenommen.

Sofern hierbei alle Dokumente ordnungsgemäß vorliegen und keine Hinweise auf eine Fehllieferung zu erkennen sind, wird die Ware von CSM Europe für die Verpackung freigegeben. Eine analytische ID-Prüfung wird nicht durchgeführt.

Der Sponsor bestätigt hiermit, daß die Ware für die Herstellung/Verpackung nach der oben beschriebenen Eingangskontrolle freigegeben werden kann und trägt somit das Risiko, wenn sich bei der Endkontrolle herausstellen sollte, daß die angelieferte Bulkware nicht der deklarierten Ware entsprach.

“Packaging on risk”

Any bulkware arrived will be checked by CSM Europe for plausibility, i.e. we perform a visual check and compare the batch numbers with the accompanying batch documentation.

If all documents are available accordingly and if there is no sign of any mistake during the delivery, the bulkware will be released for packaging. There will be no analytical ID-testing.

Sponsor confirms that the bulkware released in the way as mentioned above can be used for packaging and that it will be at sponsors' risk, if after packaging has been finished it turned out that the bulkware delivered did not correspond to the product label.

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