

[Print view complaints](#)

Complaint details (Tabcin Noche Bulk CGB - MX (G) - further see complaint form) [Signature id 393086260]

Complaint ID	2023-041165	Country	Mexico	Division	CC
Complaint type	internal	Product type	Drug product	Contact person BHC	Ricardo Ortega
Message dated	2023-07-13	Date received	2023-07-13	Entry date	2023-07-14
Complainant	I 23-079	Sender	I 23-079	Recipient of reply	I 23-079
Report source	Spontaneous				
Study ID		Study center			
Patient ID		Medication number			

Short description	Tabcin noche Bulk Capsule damage / appearance				
Complaint as reported	The production area notifies the following: During the packaging of the product 88578953 TABCIN NOCHE CAPS BLI 12 MX lot X25NXG and X25NXJ, deformed and stuck capsules were detected, causing line stoppages because they got stuck in the feeder.				
Remark					
Species	None	Type of target animal	None		

Sample available for investigation	Yes	Rational for No Sample Return/Special sample handling	Unknown		
Sample description	Three bags with capsules of the batches: MA04A0P (50pieces), MA049S0 (22pieces), MA04A3F (40pieces).		Number of complained packages	112	
			Number of received packages	0	
Sample shipping destination			Tracking number		

Manufacturing site	BPH Spain Berlimed	Contract manufacturer	No
Lead investigation unit	BPH Spain Berlimed		
Adverse event reported/PV case associated	No		
Safety database/AE reference number			
Medical Database Reference #			
Suspected counterfeit, fraud or diversion (theft, smuggling)	No	Country of origin of counterfeit	

Error / classification [Signature id 393086260]

Error code	Capsule - Damage - Leakage/not tightly closed Capsule - Damage - Breakage Capsule - Quantity - Underfilling in immediate container
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Risk classification Risk category III Notification groups -

Customer data [Signature id 393086260]

Complaint type	Complaint	CRM number			
Customer response required	Yes	Customer response required (Justification)	Customer response required (Summary)	Yes	
Additional response required	No	Additional response required (Desc.)			
Customer forbids further contact	No	Return authorization number			

Communication protocol

Customer contact counter	0
Communication protocol	

Batch/Serial data [Signature id 393086260]

Batch no	MA049S0	Material no	85023136	Show batch/material	Show material
Number of complaints for batch:	1 Show further complaint(s) for batch				
Unknown Batch no	No				
Short description(DE)	Tabcin Noche Bulk CGB - MX (G)				
Short description(EN)	Tabcin Noche Bulk CGB - MX (G)				
Order ID	001001995176	Manufacturing controller	OA1		
Production date	2023-03-07	Expiration date			
UDI					
Level producthierarchie(text)	6				
Code producthierarchie level 1(Code Main Group)	16				
Text producthierarchie level 1(Text Main Group)	Consumer Health				

Batch no	MA04A0P	Material no	85023136	Show batch/material	Show material
Number of complaints for batch:	1 Show further complaint(s) for batch				
Unknown Batch no	No				
Short description(DE)	Tabcin Noche Bulk CGB - MX (G)				
Short description(EN)	Tabcin Noche Bulk CGB - MX (G)				
Order ID	001001996234	Manufacturing controller	OA1		
Production date	2023-03-14	Expiration date			
UDI					
Level product hierarchy(text)	6				
Code product hierarchy level 1(Code Main Group)	16				
Text product hierarchy level 1(Text Main Group)	Consumer Health				
Code product hierarchy level 1-4	1627220004	Text product hierarchy level 1-4	TABCIN / COLD		
Code product hierarchy level 1-6	162722000404100415	Text product hierarchy level 1-6	TABCIN NIGHTTIME		
Unique Identifier	GTIN				

Batch no	MA04A3F	Material no	85023136	Show batch/material	Show material
Number of complaints for batch:	1 Show further complaint(s) for batch				
Unknown Batch no	No				
Short description(DE)	Tabcin Noche Bulk CGB - MX (G)				
Short description(EN)	Tabcin Noche Bulk CGB - MX (G)				
Order ID	001001996233	Manufacturing controller	OA1		
Production date	2023-03-17	Expiration date			
UDI					
Level producthierarchy(text)	6				
Code producthierarchy level 1(Code Main Group)	16				
Text producthierarchy level 1(Text Main Group)	Consumer Health				
Code producthierarchy level 1-4	1627220004	Text producthierarchy level 1-4	TABCIN / COLD		
Code producthierarchy level 1-6	162722000404100415	Text producthierarchy level 1-6	TABCIN NIGHTTIME		
Unique Identifier	GTIN				

## Gatekeeper GPV

Decision	
Recommendation	
Rational for recommendation / decision	Additional information
Do not review case after statement of RQU is available	

Assessment [Signature id 397508852]

Origin of cause	Not clear	Component involved in complaint		
Defect cause	Other / none	Unit responsible for defect	Alcala-BerliMed	
Conclusion	Unconfirmed quality defect - but plausible	Counterfeit	No	
Final assessment	The revision of the batches's documentation doesn't show any deviation during the manufacturing process. 100% of the products were reviewed in trays. In case of detect leakage deformed or stuck capsules capsules, rejection would be done before packaging. Several IPCs and flexibility control and AQLs were performed during the manufacturing of these batches with satisfactory results, no more incidents were detected. After the evaluation of the pictures and retention samples, we cannot ensure that the defect reported was provoked by the manufacturing process in Berlimed. There are two defects reported: deformed and stuck capsules by agglutination and leakage. Based on our experience, the most possible root causes identified for these types of defects are as follows: 5 WHY WHAT WHY (1) WHY (2) WHY (3) WHY (4) WHY (5) Root Cause Agglutination High temperature or humidity during storage Wrong storage conditions - - Storage leakages Pore in the shell A defect during the encapsulating process - - Manufacturing process Broken capsules Wrong handling of the product - - Mishandling during transport or reception			
	Check for similar complaints provided following results: we have not received other complaints confirmed for this reason. No trend was found.			
	Final risk classification	Risk category IV	Preliminary Statement	No
	Responsible QU	Madrid		
	Extent of defect	No assessment	Defect Category	Product physical issues - Product physical issue
Sample received at Quality Unit	No			
Final error code	<div>Capsule - Damage - Leakage/not tightly closed</div> <div>Capsule - Appearance/Product characteristics - Agglutination</div>			

Leading error code	Capsule - Appearance/Product characteristics - Agglutination
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Contract manufacturer assessment [Signature id 397508852]

Send data to contract manufacturer

Attachments to send

Send date

Received date

Quality-safety evaluation

Adverse event reported/PV case associated

No

Safety database/AE reference number

Medical Database Reference #

Quality-safety evaluation

Remarks(only for internal use)

Acknowledgements

Close [Signature id 397519566]

Corrective and preventive actions

None

Reply

Response letter

Duplicates

Duplicates

Electronic signatures

Signature id

393086260

Signature 'Elektronische Unterschrift für Erfassen/Electronic Signature for data entry' by gourq (Ortega, Ricardo (gourq)) on 2023-07-14 21:59:56

Signature id

397508852

Signature 'Elektronische Unterschrift für Bewertung/Electronic Signature for assessment' by betsu (Tena Serrano, Ruben (betsu)) on 2023-09-05 16:26:18

Signature id

397519566

Signature 'Elektronische Unterschrift Abschließen/Electronic Signature for close' by gourq (Ortega, Ricardo (gourq)) on 2023-09-05 17:52:06

Next Steps

Scheduled date

2023-08-12

Status

Closed

Attached Documents

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IMG\_20230714\_094922\_MP.jpg

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IMG\_20230714\_095001\_MP.jpg

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IMG\_20230714\_095229\_MP.jpg

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IMG\_20230714\_095050\_MP.jpg

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IMG\_20230714\_095100\_MP.jpg

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IMG\_20230714\_095011\_MP.jpg

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2023-041165\_(2023-321).pdf

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Informative copy, 2023-09-05