

# Attachment to RAN Nimesil

COMPLAINT RECORD: 2023\_25 (TW246426)  
BERLIN-CHEMIE: 29420 (Q23/RU/03)  
PRODUCT: Nimesil® 30 sachets Georgia  
BATCHES: 21010  
EXP. DATE: 01.2025

## Description:

"Please find attached all available information to the complaint Q23/RU/03 - Nimesil, granules for suspension for oral administration, 100 mg, batch no. 21010. Photos of the sample in attachment, samples are not available. (There are also no folding boxes available, the pharmacy sells the sachets without folding boxes.) The batch 21010, F133668 was produced for Georgia, see attached COA. Due to the severity of this case, in order to prevent possible harm to our consumers, we ask you to give an answer within 5 days."

## Assessment:

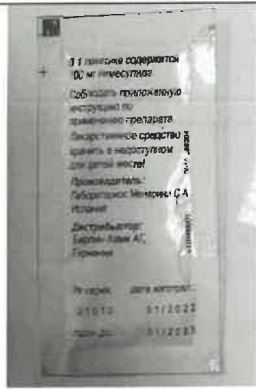
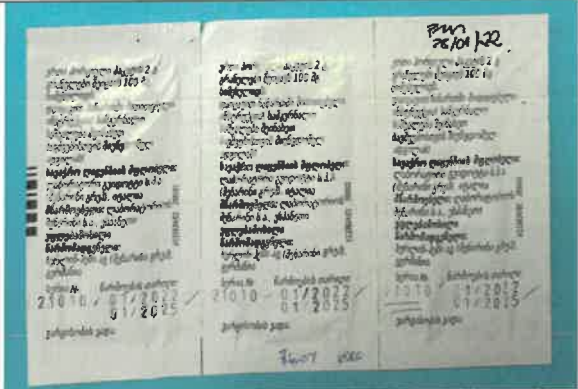

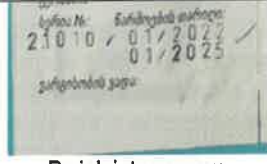




This complaint was investigated with several departments with site manufacturing responsibilities (Quality Assurance Compliance, Oral Solid Forms, Quality Assurance Operations, Logistics and Editing).

- We have reviewed the Batch Record corresponding to this batch:
  - For this product, the folding box artwork was 269001 and the sachets artwork was 269101; these were approved on 30/06/2020 and started to use on 03/07/2020 (find the approved artworks as attachments).
  - All the material samples of the Batch Record were correct.
  - This batch was packaged in sachet line 2, no incidence was detected. The previous manufactured batch was of the same product, which make it possible to discard a crossover of materials.
- Furthermore, we have verified that the artworks and sizes of the sachets and the folding box showed in the complaint images were not used in LMSA.
- We have reviewed our retained samples and all of them were correct. We reviewed eight units (4 units of 2<sup>nd</sup> box and 4 units of 95<sup>th</sup> box). We compared the complaint photos and the retained samples/batch record samples, we had observed the next differences:

Differences observed	Complaint Unit	LMSA units
Different sachet artwork		





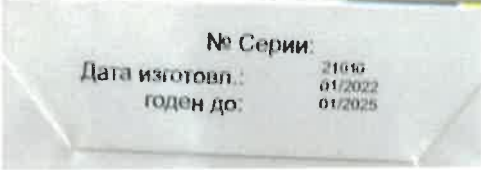
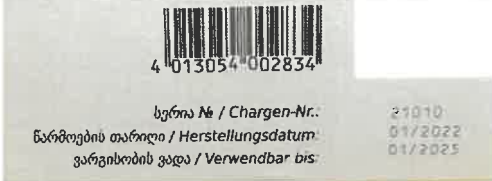


Los certificados de Sistemas de Gestión corresponden a Laboratorios Menarini, S.A

Differences observed	Complaint Unit	LMSA units
		
Different sachet size	Length: 10 cm Width: 5 cm	Length: 8 cm Width: 4 cm
Variable data marking	 By laser	 By ink jet pressure
Different folding box artwork	 	 
Different folding box size	Width: 10.7 cm	Width: 12.5 cm



Datos escritura subanador: Tomo 11.394, Fo 10 79 Hoz376453 - N.I.F. A0612918

Differences observed	Complaint Unit	LMSA units
This product does not have tamper evident.		
Sachets and leaflet distribution	 <ul style="list-style-type: none"> <li>- Individual sachets</li> <li>- Leaflet not bent and on the side</li> </ul>	 <ul style="list-style-type: none"> <li>- Pack of three sachets</li> <li>- Leaflet bent and below</li> </ul>
Variable data marking	 <p style="text-align: center;">By laser</p>	 <p style="text-align: center;">By OCS marking</p>

4. The information provided by the other departments with site manufacturing responsibilities is the next:
  - Regarding the **different sachet/folding box sizes** detected in the complaint unit, the *BK Manager (Oral Solid Forms)* informed that in LMSA the sachet and folding box size are unique. The sealing jaws format is standard and unique for all the Nimesil packaging lines. All the presentations of this product in LMSA are of triple sachets packs, never single sachets.
  - Regarding the **release and shipment** of this batch, the batch has been released on 03/02/2022 and *Logistics department* informed it was shipped on 10/02/2022 and it was received in Berlin-Chemie AG, Germany on 14/02/2022, no observation has been informed during the reception (EXP-8214).
5. Finally, we have reviewed the record of complaints received for this batch, confirming that no other complaints has been received.
6. For all these reasons, considering the investigation performed and taking into account the effectiveness of our quality system, we can conclude that this unit is not manufactured in LMSA. This complaint is considered as **NOT JUSTIFIED and the origin is external to LMSA**.



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### Corrective Actions /Preventive Actions:

**CAPA plan:** no action is required.

### Classification and Conclusion

This complaint is classified as **NOT JUSTIFIED**.

If no reply is received within 15 days, this complaint record will be closed.

If you need any further information please do not hesitate to contact us.

Badalona, February 21<sup>th</sup> 2022



Ariadna Claparols Cuquejo  
Quality Assurance Compliance Technician

