REPÚBLICA PORTUGUESA
SAÚDE

SNS
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Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

*National Authority of Medicines and Health Products, I.P.*

CERTIFICATE NUMBER: ***FT022/MH/001/2017***

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

## Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:
The manufacturer: ***Granules India Limited***
Site address: ***Plot No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Qutbullapur Mandal, Ranga Reddy District, Telangana State, Hyderabad, 500043, India***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:
***Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-12-09*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*



SGS

Fernanda Ratha
Directora da Direcção
Inspecção e Licenciament

## Part 2

| Human Medicinal Products |
|---|

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.2** | **Non-sterile products** |
| | *1.2.1 Non-sterile products (processing operations for the following dosage forms)*<br>1.2.1.13 Tablets |
| **1.5** | **Packaging** |
| | *1.5.1 Primary Packing*<br>1.5.1.13 Tablets |
| | *1.5.2 Secondary packing* |
| **1.6** | **Quality control testing** |
| | *1.6.2 Microbiological: non-sterility*<br>*1.6.3 Chemical/Physical* |

Any restrictions related to the scope of this certificate :

| Building | Room | Line/equipment | QC testing | Products |
|---|---|---|---|---|
| ***Formulation Block*** | ***Blister packing - 2*** | ***BQS (IDPRE089)*** | | ***Not authorised for primary packaging of Metformin 1000 mg tablets until IQ, OQ and PQ and blistering process validation are complete*** |

***1.5.1.13.The blister packing machine BQS (IDPRE089) is not authorised for primary packaging of Metformin 1000 mg tablets until IQ, OQ and PQ and blistering process validation are completed. The two other blistering lines (Blister packing - 1 - B45 and Blister packing - 3 - Hoonga) are authorised within the scope of this GMP Certificate. This GMP certificate is valid for 2 years from the inspection date.***

Clarifying remarks (for public users)

***1.5.1.13.The blister packing machine BQS (IDPRE089) is not authorised for primary packaging of Metformin 1000 mg tablets until IQ, OQ and PQ and blistering process validation are completed. The two other blistering lines are authorised within the scope of this GMP Certificate. This GMP certificate is valid for 2 years from the inspection date.***



Fernanda Ralha
Directora da Direcção
Inspecção e Licenciamento

*2017-02-24*

Name and signature of the authorised person of the Competent Authority of Portugal

***Ms. Maria Fernanda Ralha Henriques Matos***
***National Authority of Medicines and Health Products, I.P.***
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