

VPA10387/001/001

Aurofac Granular 250 mg/g Premix for medicated feedingstuff for pigs and chickens

| Variation | Summary | Date |
|-------------------|---|----------|
| Vet - F.II.c.1 c) | VRA-R - Vet - F.II.c.1 c) - c) Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method, as a result of a safety or quality issue - F.II.c.1 c) Quality Changes - Finished Product -Control of excipients-Change in the specification parameters and/or limits of an excipient - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method, as a result of a safety or quality issue | 09/09/24 |
| Vet - F.I.d.1 c) | VRA-S - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data | 03/07/24 |
| Vet - B44 | VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient | 24/05/23 |
| Vet - G.I.18 | VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 | 20/02/23 |
| Vet - B34 | VNRA - Vet - B34 - Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product - B34 Changes to the quality part of the dossier: Change in qualitative and quantitative composition of the immediate packaging for a solid | 15/07/22 |

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| | pharmaceutical form for a finished product | |
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