

PN0401/13

Dr. Nagy



Zoetis Medolla Manufacturing S.r.l.

Documento N°: MOD QS-022.04-V01

Unità Operativa: Quality Assurance

Titolo: Modulo Certificazione QP (Batch Release Certificate)

### BATCH RELEASE CERTIFICATE

Product Name: AUROFAC Granular 250 mg/g

Batch number: AFH37476      Product Code: 703130

Batch Size: 1000 Kg      Packaging Type/size: Bags 20 Kg

Monograph N°: 005-V00

Manufacturing date: September 2013      Retest date: August 2016

I hereby certify that the above information is authentic and accurate.  
 This batch of product has been manufactured, including packaging/labeling and quality control at the above mentioned site(s), in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.  
 Certificate of Analysis is attached.

This is also to certify that, where applicable, any materials animal-derived used in the manufacture and/or formulation of the batch of product specified above fulfill the prescriptions defined in Commission Directive EMEA/410/01 and have therefore been demonstrated to be in accordance with the current CPMP "Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products", through the Ph Euro Certification procedure.

Comments/Remarks: No

Final Disposition: RELEASED

Signed by: Maurizio Meazza      Date: 16 SET 2013

Qualified Person, Medolla Site  
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 maurizio.meazza@zoetis.com

Certificate N°: QPC-13/00469

Zoetis Medolla Manufacturing S.r.l.

**CERTIFICATE OF ANALYSIS**AUROFAC 250 MG/G GRANULAR  
HUNGARY

Active substance : Chlortetracycline hydrochloride  
 Lot no. : AFH37476  
 Month of manufacture : September 2013  
 Month of expiration : August 2016

TEST ITEMS	SPECIFICATIONS	RESULTS
Appearance	Granular solid	Complies
Colour	Yellow	Complies
Identification (HPLC)	Complies	Complies
Particle size	Max. 6% > 1,180 mm	0,8%
	Max. 15% < 0,300 mm	8,5%
Moisture	≤ 2,0%	0,1%
Assay – CTC.HCl content	23,75% - 26,25%	24,94%
Individual specified related substances (as % of CTC.HCl)	4-epiCTC.HCl ≤ 4,0%	2,6%

Signed by:



Medolla, September 16, 2013  
 per Zoetis Medolla Manufacturing S.r.l.

Certificate N°: A13/00469