

Analysenzertifikat / Certificate of Analysis

Produkt / product : **Wismutsubgallat / Bismuth Subgallate**
 CAS-Nr. / CAS-no. : **99-26-3**
 Qualität / quality : **PharmEuro 8.0**
 Charge / batch : **2015007568**

Produktionsdatum / date of manufact. : 09.2015
 Analysendatum / date of analysis : 10.2015
 Nachkontrollfrist / Re-test date : 5 years after date of manufacturing

Kunde / customer : Fagron Services B.V.
 Liefermenge / quantity : 300 kg
 Rechnungsnr. / invoice no. : 1190050536
 Auftragsnr. / order no. : BI151638

Prüfparameter / test	Messwert / result	Spezifikation / spec
Aussehen/ appearance	Gelbes Pulver / yellow powder	Gelbes Pulver / yellow powder
Identitäten A, B / identification A, B	Entspricht / pass test	Entspricht / pass test
Mit Ammoniak nichtfällbare Subst. / subst. not precipitated by ammonia	< 0.1 %	max. 1.0 %
Sauer reagierende Substanzen/ acidity	Entspricht / pass test	Entspricht / pass test
Chlorid / chlorides	< 200 ppm	< 200 ppm
Nitrat / nitrates	< 0.2 %	< 0.2 %
Blei / lead	< 20 ppm	< 20 ppm
Kupfer / copper	< 50 ppm	< 50 ppm
Silber / silver	< 25 ppm	< 25 ppm
Trocknungsverlust / loss on drying	4.8 %	max. 7.0 %
Wismutgehalt, trocken / assay	50.6 %	48.0 – 51.0 %

This batch of bismuth subgallate was manufactured in accordance with GMP rules (ICH Q7). It complies with the compendial requirements of the Ph. Eur. monograph for bismuth subgallate. Site of manufacture is 5N Plus Lübeck GmbH, Lübeck (Germany).

Released by quality assurance

Lübeck, 21. Oktober 2015

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