

**Product:** DIOSMIN EP  
**Customer:** META-PHARMACEUTICAL INDUSTRIAL S.L.  
**Customer order number:** 2019-1/233  
**DBCh Order No.:** ORD19-003670  
**Batch No.:** DF-5597  
**Nett Weight:** 500 Kg

**Code:** 0538

DEFINITION	RESULTS	SPECIFICATIONS (*)	METHOD
<b>Identification:</b> (by IR & HPLC)	Positive	positive	According to std.
<b>Appearance:</b>	Conform	greyish-yellow or light yellow hygroscopic powder	According to std.
<b>Solubility:</b>	Conform	practically insoluble in water, soluble in dimethyl sulfoxide, practically insoluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides	According to std.
<b>Decomposition point:</b> (°C)	274.0	272-283	Current EP
<b>Water content:</b> (%)	2.22	≤ 6.0	Current EP
<b>Diosmin content:</b> by HPLC (%)	91.00	≥ 90.0-102.0 (on anhydrous substance)	Current EP
<b>Imp. A (Acetoisovanillone):</b> (%)	0.11	Max. 0.5	Current EP
<b>Imp. B (Hesperidin):</b> (%)	0.64	Max. 4.0	Current EP
<b>Imp. C (Isorhoifolin):</b> (%)	2.08	Max. 3.0	Current EP
<b>Imp. D (6-Iododiosmin):</b> (%)	<0.10	Max. 0.6	Current EP
<b>Imp. E (Linarin):</b> (%)	2.05	Max. 3.0	Current EP
<b>Imp. F (Diosmetin):</b> (%)	0.70	Max. 2.0	Current EP
<b>Any others impurities:</b> (%)	<0.4	Max. 0.4	Current EP
<b>Total impurities:</b> (%)	5.79	Max. 8.5	Current EP
<b>Sulfated ashes:</b> (%)	0.13	Max. 0.2	Current EP
<b>Heavy metals:</b> (ppm)	<20	Max. 20	Current EP
<b>Iodine content:</b> (%)	<0.1	Max. 0.1	Current EP
<b>Residual solvent:</b> (ppm)	<200	(Piridine) Max. 200	Internal method
	<5000	(Acetic acid) Max. 5000	Internal method
<b>Aerobic Bact.:</b> (cfu/g)	<10 <sup>3</sup>	Max. 10 <sup>3</sup>	Current EP
<b>Coliform Bact.:</b> (cfu/g)	Absent	Absence (1g)	Current EP
<b>E. Coli:</b>	Absent	Absence (1g)	Current EP
<b>Yeast/Moulds:</b> (cfu/g)	< 10 <sup>2</sup>	Max. 10 <sup>2</sup>	Current EP
<b>Particle size:</b> (%/µm)	Conform	100% < 100 µm	Current EP
<b>Bulk density:</b> (g/ml)	Conform	< 0.5	Current EP

(\*) Revised: February 2019. Rev.16

MANUFACTURING DATE: 23 January 2020

REANALYSIS\*\*: 21 January 2025

Date: 10 February 2020

Quality Control Manager:



The results of the tests exposed in this Certificate of Analysis were determined immediately after production. Therefore Destilaciones Bordas Chinchurreta, S.A. does not assume responsibility for the variation of its properties caused by inadequate transport or storage of product in question. This Certificate does not exempt the customer from his own quality check.  
Storage conditions: Keep at room temperature in a dark and dry place.

DESTILACIONES BORDAS CHINCHURRETA, S.A.

Acueducto, 4-6 Pol. Ind. Carretera la Isla 41703 - Dos Hermanas - Sevilla - Spain  
Tel.: +(34) 95 4419000 • Fax: +(34) 95 4417152 • bordas@bordas-sa.com • www.bordas-sa.com • VAT: ES A-41001454

*(\*\*) After this period the product should keep all its quality if stored under the appropriate conditions. If the analysis conforms the specifications, the product can be used and reanalysed after 3 months.*

---

