

Product: DIOSMIN EP
Customer: META-PHARMACEUTICAL INDUSTRIAL S.L.
Customer order number: 231
DBCh Order No.: ORD19-005093
Batch No.: DF-5593
Nett Weight: 500 Kg

Code: 0538

DEFINITION	RESULTS	SPECIFICATIONS (*)	METHOD
Identification: (by IR & HPLC)	Positive	positive	According to std.
Appearance:	Conform	greyish-yellow or light yellow hygroscopic powder	According to std.
Solubility:	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.
Decomposition point: (°C)	274.5	272-283	Current EP
Water content: (%)	3.32	≤ 6.0	Current EP
Diosmin content: by HPLC (%)	91.4	≥ 90.0-102.0 (on anhydrous substance)	Current EP
Imp. A (Acetoisovanillone): (%)	0.12	Max. 0.5	Current EP
Imp. B (Hesperidin): (%)	0.19	Max. 4.0	Current EP
Imp. C (Isorhoifolin): (%)	1.47	Max. 3.0	Current EP
Imp. D (6-Iododiosmin): (%)	<0.10	Max. 0.6	Current EP
Imp. E (Linarin): (%)	2.16	Max. 3.0	Current EP
Imp. F (Diosmetin): (%)	0.52	Max. 2.0	Current EP
Any others impurities: (%)	<0.4	Max. 0.4	Current EP
Total impurities: (%)	4.73	Max. 8.5	Current EP
Sulfated ashes: (%)	0.19	Max. 0.2	Current EP
Heavy metals: (ppm)	<20	Max. 20	Current EP
Iodine content: (%)	<0.1	Max. 0.1	Current EP
Residual solvent: (ppm)	<200	(Piridine) Max. 200	Internal method
	<5000	(Acetic acid) Max. 5000	Internal method
Aerobic Bact.: (cfu/g)	<10 ³	Max. 10 ³	Current EP
Coliform Bact.: (cfu/g)	Absent	Absence (1g)	Current EP
E. Coli:	Absent	Absence (1g)	Current EP
Yeast/Moulds: (cfu/g)	< 10 ²	Max. 10 ²	Current EP
Particle size: (%/µm)	Conform	100% < 100 µm	Current EP
Bulk density: (g/ml)	Conform	< 0.5	Current EP

(*) Revised: February 2019. Rev.16

MANUFACTURING DATE: 22 August 2019
 REANALYSIS**: 20 August 2024
 Date: 05 September 2019

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.

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*(**) 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.*

