

Certificate of Analysis

Product name : COMPRITOL 888 ATO

Item N° : 3123ACC
Batch N° : 193164
Manufacturing date : 12.2022
Expiry date : 11.2025
Specification N° : 3123/19

METAPHARMACEUTICAL

N DE LOTE:

0260423

Customer reference : GATTEFOSSE ESPANA

Customer code : S008

Delivery N° : 80317898

Analysis date : 12.2022
Inspection lot : 40000100905

VAT N°: ES-B58736869 - www.metapharmaceuti

CHEMICAL DEFINITION :

Glycerol dibehenate EP current edition/ Glyceryl dibehenate
NF current edition / Glyceryl behenate Ch. P current edition.

Characteristic	Method	Specification	Result
MANUFACTURING PLANT		Gattefossé : 01 / SIO : 02 / Innovia : 06	02/01
APPEARANCE	MA0193	Fine powder	Conforms
ODOUR	MA0170	Faint	Conforms
COLOUR (Gardner Scale)	MA0214	< = 5.0	0.7
DROP POINT (METTLER)	MA0003	69.0 to 74.0 °C	73.1
MELTING POINT (Cap. tube)	MA0167	65.0 to 77.0 °C	65.0 to 77.0*
ACID VALUE	MA0008	< = 4.00 mgKOH/g	1.76
SAPONIFICATION VALUE	MA0172	145 to 165 mgKOH/g	150
IODINE VALUE	MA0092	< = 3.0 gI2/100g	< = 3.0*
PEROXIDE VALUE	MA0010	< = 6.0 meqO2/kg	< 0.1
FREE GLYCEROL CONTENT	MA0006	< = 1.0 %	0.7
1-MONOGLYCERIDES CONTENT	MA0006	12.0 to 18.0 %	15.9
TOTAL MONOGLYCERIDES CONTENT	MA0006	15.0 to 23.0 %	17.7
TOTAL DIESTERS CONTENT	MA0006	40.0 to 60.0 %	51.2
TOTAL TRIESTERS CONTENT	MA0006	21.0 to 35.0 %	29.3
PALMITIC ACID (C16)	MA0002	< = 3.0 %	0.2
STEARIC ACID (C18)	MA0002	< = 5.0 %	2.6
ARACHIDIC ACID (C20)	MA0002	< = 10.0 %	7.0
BEHENIC ACID (C22)	MA0002	> = 83.0 %	87.9
ERUCIC ACID (C22:1)	MA0002	< = 1.0 %	< 0.1
LIGNOCERIC ACID (C24:0)	MA0002	< = 3.0 %	1.9
RESIDUE ON IGNITION	MA0028	< = 0.1 %	< = 0.1*
TOTAL ASHES CONTENT	MA0028	< = 0.10 %	< = 0.10*
WATER CONTENT	MA0007	< = 1.0 %	0.1
NICKEL CONTENT	MA0256	< 1 ppm	Conforms *
HEAVY METALS CONTENT (Pb)	MA0032	< 10 ppm	Conforms *
RESIDUAL SOLVENTS (Eur. Pharm., USP/NF)		Meets the requirements (production without solvent)	Conforms *
ARSENIC CONTENT	MA0323	< 2 ppm (expressed in AS2O3)	Conforms *



Certificate of Analysis

Product Name : COMPRITOL 888 ATO

Item N° : 3123ACC

Batch N° : 193164

Characteristic	Method	Specification	Result
POLYOXYLETHYLENE (JSFA)	MA0334	No change of chloroform layer to blue.	Conforms *
JSFA Identification (Test N° 1 and 2)	MA0335	Conforms	Conforms *
EUR. PHARM., USP/NF, JSFA, ChP		Conforms to the monographs	Conforms *

* Characteristic guaranteed but not tested.

This batch was released by our authorized Quality Manager and was found to meet the specifications as stated above. The above results do not discharge the customer from the obligation to carry out an inspection of goods received.

This report has been produced electronically and does not require a signature.

Printing Date : 02.08.2023

Product Quality Manager
Emilie MOULIN