

Manufacturing site is certified according to ISO9001,  
ISO14001 and ISO45001 standards.

Certificate prepared at

Croda Europe Limited  
c/o Croda Ibérica SA, Mevisa Site  
Carretera C-35 Km 72  
08495 Fogars de la Selva, Spain

**METAPHARMACEUTICAL**

03 MAYO 2023

N DE LOTE:

0040523

Customer details

METAPHARMACEUTICAL INDL., S.L.  
C/Josep Plà, 163. 2<sup>a</sup> 5<sup>a</sup>  
08020 Barcelona  
Spain  
Fax No. 93 303 17 50

Customer Ref. 2023-1/195  
Inspection Lot 040001333928  
C of A Printed. 25.04.2023  
Croda Order No. 4098871  
Croda Del. No. 800728486  
Quantity. 100,000 KG

Batch Details

Product Name: SPAN 83 PHARMA-LQ-(MV)  
Product Code: SDR2101/0020/RP02  
Batch No: 0002157709

Date of test: 24.03.2023  
Date of manufacture: 19.03.2023  
Retest date: 18.03.2025

Specification: CREATED 28-APR-2021

Quality Control Results

Analytical Test

Method No.	Characteristic	Specification Limit		Value	Unit	Status
		Lower	Upper			
	Addendum 00	PASS OR FAIL		Pass	-	P
	REVISION NUMBER	0.0		Pass	-	P
	MATERIAL CONFORMS TO	CURRENT PhEur		Pass	-	P
	MONOGRAPH NAME	SORBITAN SESQUIOLEAT E		Pass	-	P
AR010260	APPEARANCE (CLARITY)	CLEAR/SLIGHTLY HAZY MAY FORM SEDIMENT		Pass	-	P
AR010270	APPEARANCE (COLOUR)	YELLOW TO BROWNISH YELLOW		Pass	-	P
AR010280	APPEARANCE (FORM)	VISCOUS LIQUID		Pass	-	P
ER020020	SAPONIFICATION VALUE	145	160	158	mg KOH/g	P
ER020040	IODINE VALUE	70	80	79	g/100g	P
ER020030	HYDROXYL VALUE	185	215	209	mg KOH/g	P
ER071200	PEROXIDE VALUE	0	3	1	meq/kg	P
ER098600	WATER CONTENT	0,0	1,0	0,2	%w/w	P
ER020010	ACID VALUE	0	12	9	mg KOH/g	P
LR020710	COLOUR	0	7	5	Gardner	P
FR020100	SULPHATED ASH	0.5% w/w MAX		Pass	-	P
LR020290	MYRISTIC ACID C14	0,0	5,0	0,1	%w/w	P
LR020290	PALMITIC ACID C16	0,0	16,0	4,8	%w/w	P
LR020290	PALMITOLEIC ACID C16:1	0,0	8,0	1,5	%w/w	P
LR020290	MARGARINIC ACID C17	0,0	0,2	0,1	%w/w	P



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LR020290	STEARIC ACID C18	0,0	6,0	1,4 %w/w	P
LR020290	OLEIC ACID C18:1	65,0	88,0	74,6 %w/w	P
LR020290	LINOLEIC ACID C18:2	0,0	18,0	14,8 %w/w	P
LR020290	LINOLENIC ACID C18:3	0,0	4,0	1,1 %w/w	P
LR020290	>C18	0,0	4,0	1,4 %w/w	P

This Product has been manufactured and tested to GMP in accordance with EXCiPACT.

This product conforms to ICH Q3C Residual solvents Option 1.

**Batch Status:** Pass

The quality tests on this batch are reported above. The tests carried out are those necessary to demonstrate compliance with our product specification and are not intended to guarantee the product as suitable for any application beyond those contained in the specification. We recommend you perform your own quality and or identification checks on receipt

The name printed at the end of this document is an electronic signature.

Confirmed by

Juan Ferreira QC Manager

Date 24.03.2023

Time 08:16:59