

A quality management system registered to the international standard
ISO 9001 was used to manufacture and test this material.

Certificate prepared at

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

Customer details

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

Customer Ref. 2024 - 1 / 203
Inspection Lot 040001427873
C of A Printed. 17.05.2024
Croda Order No. 4331501
Croda Del. No. 801020579
Quantity. 80,000 KG

Batch Details

Product Name: SPAN 83 PHARMA-LQ-(MV)
Product Code: SDR2101/0020/RP02
Batch No: 0002303282

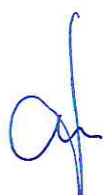
Date of test: 06.05.2024
Date of manufacture: 29.04.2024
Retest date: 29.04.2026

Specification: CREATED 28-APR-2021

Quality Control Results

Analytical Test		Specification Limit		Value	Unit	Status
Method No.	Characteristic	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		Pass	-	P
AR010270	APPEARANCE (COLOUR)	MAY FORM SEDIMENT YELLOW TO BROWNISH YELLOW		Pass	-	P
AR010280	APPEARANCE (FORM)	VISCOUS LIQUID		Pass	-	P
ER020020	SAPONIFICATION VALUE	145	160	159	mg KOH/g	P
ER020040	IODINE VALUE	70	80	76	g/100g	P
ER020030	HYDROXYL VALUE	185	215	192	mg KOH/g	P
ER071200	PEROXIDE VALUE	0	3	0	meq/kg	P
ER098600	WATER CONTENT	0,0	1,0	0,2	%w/w	P
ER020010	ACID VALUE	0	12	7	mg KOH/g	P
LR020710	COLOUR	0	7	6	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	4,6	%w/w	P
LR020290	PALMITOLEIC ACID C16:1	0,0	8,0	1,4	%w/w	P
LR020290	MARGARINIC ACID C17	0,0	0,2	0,1	%w/w	P

METAPHARMACEUTICAL

 17/05/2024

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	C/Josep Plà, 163. 2º 5ª	Inspection Lot	040001427873
	08020 Barcelona	C of A Printed.	17.05.2024
	Spain	Croda Order No.	4331501
Fax No.	93 303 17 50	Croda Del. No.	801020579
		Quantity.	80,000 KG

LR020290	STEARIC ACID C18	0,0	6,0	1,5	%w/w	P
LR020290	OLEIC ACID C18:1	65,0	88,0	76,1	%w/w	P
LR020290	LINOLEIC ACID C18:2	0,0	18,0	13,4	%w/w	P
LR020290	LINOLENIC ACID C18:3	0,0	4,0	1,1	%w/w	P
LR020290	>C18	0,0	4,0	1,1	%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 06.05.2024
Time 14:38:02