

## **Certificate of Analysis**

Lote 00504201

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 SA, 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.

40000217

Inspection Lot

040000980374

C of A Printed.

02.04.2020

Croda Order No. 3265350 Croda Del. No.

83724104

Quantity.

40,000

KG

**Batch Details** 

**Product Name: Product Code:** 

SPAN 83-LQ-(MV) SDR0934/0020/RP02

**Batch No:** 

0001590534

Date of test:

12.09.2019

Date of manufacture:

03.09.2019

Retest date:

02.09.2021

Specification:

AMENDED 11-APR-2018

## **Quality Control Results**

Analytical Test		Specification Limit				
Method No.	Characteristic	Lower	Upper	Value	Unit	Status
	Addendum 00	PASS OR FAIL		Pass	-	Р
	REVISION NUMBER	7.0		Pass		Р
	MATERIAL CONFORMS TO	CURRENT PhEur		Pass	-	Р
	MONOGRAPH NAME	SORBITAN SESQ E	UIOLEAT	Pass	-	Р
AR010260	APPEARANCE (CLARITY)	CLEAR/SLIGHTLY MAY FORM SEDIN	Pass	-	Р	
AR010270	APPEARANCE (COLOUR)	YELLOW TO BROWNISH YELL		Pass	-	Р
AR010280	APPEARANCE (FORM)	VISCOUS LIQUID		Pass	n	Р
ER020020	SAPONIFICATION VALUE	145	160		mg KOH/g	Р
ER020040	IODINE VALUE	70	80		g/100g	Р
ER020030	HYDROXYL VALUE	185	215	212	mg KOH/g	Р
ER071200	PEROXIDE VALUE	0	3	1	meq/kg	Р
ER098600	WATER CONTENT	0,0	1,0	0,5	%w/w	Р
ER020010	ACID VALUE	0	12	8	mg KOH/g	Р
LR020710	COLOUR	0	7	7	Gardner	Р
FR020100	SULPHATED ASH	0.5% w/w MAX		Pass		Р
LR020290	MYRISTIC ACID C14	0,0	5,0		%w/w	Р
LR020290	PALMITIC ACID C16	0,0	16,0		%w/w	Р
LR020290	PALMITOLEIC ACID C16:1	0,0	8,0	1,0	%w/w	Р
LR020290	MARGARINIC ACID C17	0,0	0,2	0,2	%w/w	Р



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83724104 40,000

KG

LB020290	STEARIC ACID C18	0,0	6,0	1,4	%w/w	Р
LR020290	OLEIC ACID C18:1	65,0	88,0	79,0	%w/w	Р
LR020290	LINOLEIC ACID C18:2	0,0	18,0	13,2	%w/w	Р
LR020290	LINOLENIC ACID C18:3	0,0	4,0		OF OR POST SINE	P
LR020290	>C18	0,0	4,0	0,9	%w/w	Р

This product conforms to ICH Residual solvents.

. May form a sediment at low temperatures; to clarify the product heat to 40°C and stir/agitate until homogeneous.

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