

Certificate of Analysis

Hepeat printout

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

Lote: 00+1216

Customer details

METAPHARMACEUTICAL INDL., S.L.

C/Josep Plà, 163. 2º 5ª 08020 Barcelona

Spain

Fax No.

93 303 17 50

Customer Ref. Inspection Lot 2016-1/445 040000721573

C of A Printed. Croda Order No. 2337603

29.11.2016

Croda Del. No.

82603519

Quantity.

100,000

KG

Batch Details

Product Name: Product Code:

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

Batch No:

0001156979

Date of test:

23.09.2016

Date of manufacture:

09.09.2016

Retest date:

09.09.2018

Specification:

AMENDED 15-JAN-2016

Quality Control Results

Analytical Test		Specification Limit				
Method No.	Characteristic	Lower	Upper	Value	Unit	Status
	Addendum 00	PASS OR FAIL		Pass	-	Р
	REVISION NUMBER	6.0		Pass	-	Р
	MATERIAL CONFORMS TO	CURRENT PhE	ur	Pass	-	Р
	MONOGRAPH NAME	SORBITAN SES	QUIOLEAT	Pass	-	Р
AR010260	APPEARANCE (CLARITY)	CLEAR/SLIGHTLY HAZY MAY FORM SEDIMENT		Pass	-	Р
AR010270	APPEARANCE (COLOUR)	YELLOW TO BROWNISH YELLOW		Pass	-	Р
AR010280	APPEARANCE (FORM)	VISCOUS LIQUID		Pass	-	Р
ER020020	SAPONIFICATION VALUE	145	160	157	mg KOH/g	Р
ER020040	IODINE VALUE	70	80	77	g/100g	Р
ER020030	HYDROXYL VALUE	185	215	210	mg KOH/g	Р
ER071200	PEROXIDE VALUE	0	3	2	meq/kg	Р
ER098600	WATER CONTENT	0,0	1,0	0,1	%w/w	Р
ER020010	ACID VALUE	0	12	8	mg KOH/g	Р
LR020710	COLOUR	0	7	6	Gardner	Р
LR016170	HEAVY METALS	10 MGPB/KG MAX		Pass	-	Р
FR020100	SULPHATED ASH	0.5% w/w MAX		Pass	-	Р
LR020290	MYRISTIC ACID C14	0,0	5,0	0,0	%w/w	Р
LR020290	PALMITIC ACID C16	0,0	16,0	4,3	%w/w	Р
LR020290	PALMITOLEIC ACID C16:1	0,0	8,0	0,7	%w/w	Р



Certificate of Analysis

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.

2016-1/445

Inspection Lot

040000721573

C of A Printed. Croda Order No. 2337603

29.11.2016

Croda Del. No. Quantity.

82603519

100,000

KG

LR020290	MARGARINIC ACID C17	0,0	0,2	0,1	%w/w	Р
LR020290	STEARIC ACID C18	0,0	6,0	1,6	%w/w	Р
LR020290	OLEIC ACID C18:1	65,0	88,0	78,9	%w/w	Р
LR020290	LINOLEIC ACID C18:2	0,0	18,0	12,3	%w/w	Р
LR020290	LINOLENIC ACID C18:3	0,0	4,0	1,1	%w/w	Р
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

Marta Cabrera QA Manager