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AZELIS DEUTSCHLAND PHARMA GMBH
STANDORT KREFELD
WEESERWEG 23
47804 KREFELD
ALLEMAGNE

Certificate of analysis

Print Date
07.11.2014
Purchase order Item/Date
7861 / 06.17.2014
Delivery Item/Date
80330085 900001 / 07.10.2014
Order Item/Date
144293 000010 / 06.17.2014
Customer No.
1071081
Truck number / Seal number
DNAR858/

Material: Our / Your reference

11070 RHODINE 3020 / ACETYLSALICYLIC ACID DRUM 50 KG / 1108702
RHODIA PDS : 230 FP RHO3020.2 - Dec 2010
NOVACYL PDS : ASA-3020-EP-1110-V1

This product complies with the specifications of the current editions of USP and Ph.EUR. Our Rhodine is periodically checked in microbiology by CARSO LSEH of Lyon in accordance with the European Pharmacopeia. This batch of Rhodine was manufactured in accordance with EU GMP Volume 4 Part II (ICH Q7) and with current files [R2-CEP 1993-007] and [US DMF N°11373].
* Compliance guaranteed, skip testing.

Batch: FRH1415011 / Manufacturing date: 05.30.2014 / Re-test date: 05.30.2017
Delivered quantity: 3.000 KG Batch quantity: 13.600 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
Identity	-	Guaranteed conformity-	-	-
Ph. Eur. / USP	-	-	-	-
Ethanollic sol.-colour	-	Liquid less coloured than B9 -	-	-
Ph. Eur.	-	-	-	-
Ethanollic sol.-turbidity	-	Clear	-	-
Ph. Eur.	-	-	-	-
Loss on drying	%	< 0,01	-	0,50
Ph. Eur.	%	99,8	99,5	101,0
Assay (on a dry basis)	%	< 0,01	-	0,05
Ph. Eur.	ppm	< 10	-	10
Sulphated ash	%	< 0,0300	-	0,1500
Ph. Eur. / USP	%	< 0,0300	-	0,1500
Heavy Metals	%	< 0,0300	-	0,1500
Ph. Eur. / USP	%	< 0,0300	-	0,1500
Anhydride of acetylsalicylic acid	%	< 0,0300	-	0,1500
HPLC	%	< 0,0300	-	0,1500
Acetylsalicylsalicylic acid	%	< 0,0300	-	0,1500
HPLC	%	< 0,0300	-	0,1500

R3020-EUR-2
1 - 12.20.2012

Die Angaben auf dem Analysenzertifikat entbinden den Käufer nicht von der Durchführung einer vollständigen Wareneingangskontrolle.
The results on the Certificate of Analysis do not absolve the buyer from a full analytical control.

Material: Our / Your reference

11070 RHODINE 3020 / ACETYLSALICYLIC ACID DRUM 50 KG / 108702

RHODIA PDS : 230 FP RHO3020.2 - Dec 2010

NOVACYL PDS : ASA-3020-EP-1110-V1

Batch: FRH1415011 / Manufacturing date: 05.30.2014 / Re-test date: 05.30.2017

Delivered quantity: 3.000 KG

Batch quantity: 13.600 KG

Salicylsalicylic acid	%	0,0300	0,1500
HPLC			
4-hydroxybenzoic acid	%	0,0300	0,1500
HPLC			
4-hydroxyisophtalic acid	%	< 0,0300	0,1500
HPLC			
Free salicylic acid	%	< 0,0300	0,1500
HPLC			
Unspecified impurities > 0.05%	-	None	-
HPLC			
Sum of related substances		< 0,03	0,25
HPLC			
Retained on 180 mu sieve		85,3	60,0
FRITSCH			
Retained on 710 mu sieve		1,7	5,0
FRITSCH			

Batch released on : 06.05.2014

Person responsible for batch release: Bernard CORRIAS

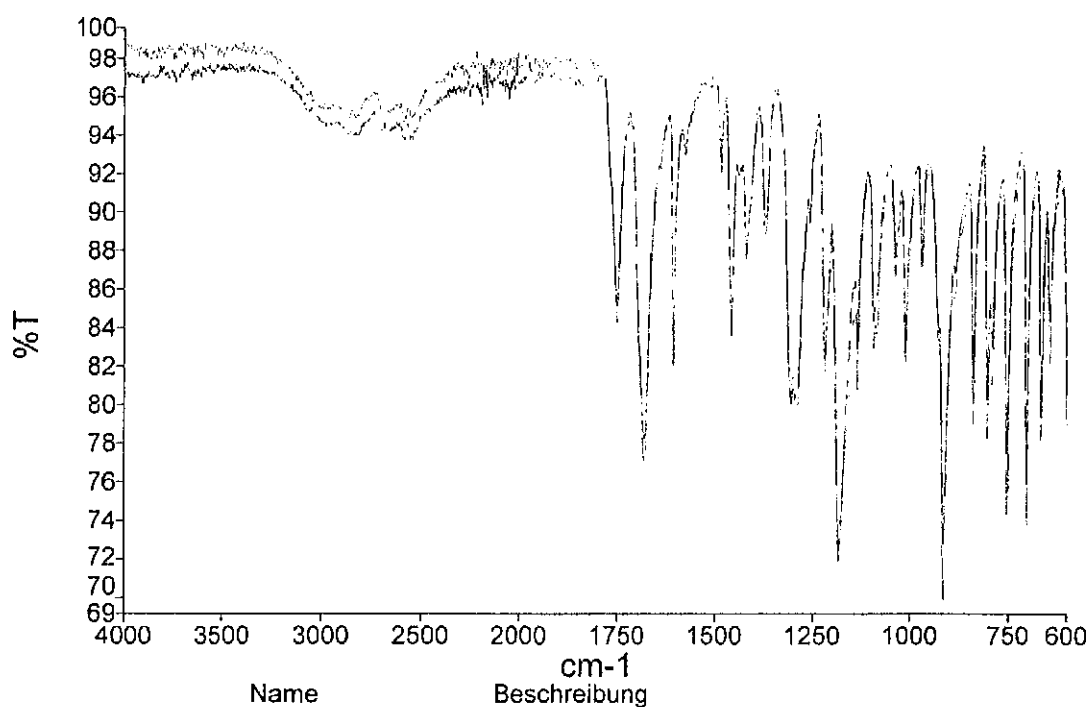
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Chargenfreigabe

Benutzer:	Feller	Datum:	11.07.2014 13:36:18
Item-Nr.:	108702	Charge:	FRH1415011
Bezeichnung:	Rhodine 3020		
Ref. Spektrum:	R_108702_1.sp		
Ist-Korrel.:	0,9863		

Probe wurde als Rhodine 3020 identifiziert



Name	Beschreibung
108702_FRH1415011.sp	
R_108702_1.sp	Rhodine 3020, Ref.

Freigabe Leitung Qualitätskontrolle

11.07.2014