

NOVACYL SAS
29 AVENUE JOANNÈS MASSET
Le Carré Joannès - CS 10619
69009 - LYON
FRANCE

Certificate of analysis

Print date:
21.03.2012
Purchase order item/Date
487/2012 / 07.03.2012
Delivery item/Date
82106703 900001 / 02.04.2012
Order item/Date
1334347 000010
Customer
74420
Truck number/Seal number
/

Attn:
FAX:

Material: Our / Your reference
11186 PHARMA SALICYLIC ACID 40X25KG PAPER BAG /PAL 1000 KG /

This batch of salicylic acid was manufactured in accordance with EU GMP Volume 4 Part II (ICH Q7A) and according to the dossier R2-CEP 1993-008. It complies with all compendial requirements of the current Ph. Eur. monograph on salicylic acid

* Statistical control: This result comes from a weekly measure

Batch RAS1206700 /Manufacturing date 07.03.2012/Re-Test date 07.03.2017
Quantity 6.000 KG

Characteristic	Unit	Value	Lower Limit	Upper Limit
Sol. in 95/96 % ethanol	-	In specification	-	-
Colouration of ethanolic sol.	HAZEN	< 10	-	10
Sulfates (SO4--)	%	0,0150	-	0,0200
Assay	%	100,3	99,0	100,5
* Heavy Metals (PB)	%	< 0,0010	-	0,0020
* Chlorides (Cl-)	%	< 0,0025	-	0,0100
* Ash Sulphated	%	0,0240	-	0,1000
4-hydroxybenzoic acid	%	0,0410	-	0,1000
4-hydroxyisophthalic acid	%	0,0270	-	0,0500
Phenol	%	< 0,0060	-	0,0100
Total impurities	%	< 0,12	-	0,20
No other relat. subst.>0,05%	-	In specification	-	-
Loss on drying	%	0,08	-	0,50

Batch released on :21.03.2012
"Isabelle COSTET, Quality Manager/cGMP ; +33 474 113 876"

SALIPH-PE-2
1 01.11.2011


correspondance à l'ote. 122003-

9-04-13