

Novacyl

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Certificate of analysis

Print Date
02.04.2016
Purchase order Item/Date
040999 / 02.04.2016
Delivery Item/Date
80393441 900001 / 02.15.2016
Order Item/Date
178305 000010 / 02.04.2016
Customer N°
4459
Truck number /Seal number
/

Material: Our / Your reference

11186 PHARMA SALICYLIC ACID 40X25KG PAPER BAG / PAL 1000 KG / 109406

This batch of salicylic acid was manufactured in accordance with ICHQ7 and Eudralex Volume 4 Part 2 GMP requirements. It complies with the requirements of current version of Ph.Eur. and USP and with the current revision of R2-CEP-1993-008.

Residual solvents: No class 1, 2 or 3 solvents are used in the salicylic acid process. Therefore, there are no residual solvents likely to be present.

Batch: RAS1533500 / Manufacturing date: 12.01.2015 / Re-test date: 11.30.2020
Delivered quantity: 3.000 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
IR spectrum	-	Complies	-	-
Melting point	°C	158,9	158,0	161,0
Location of main assay peak(USP)	-	Complies	-	-
Loss on drying	%	0,1	-	0,5
Sulfates	%	0,0170	-	0,0200
Assay EP (dry basis)	%	100,4	99,0	100,5
Assay USP (dry basis)	%	99,5	98,0	102,0
Clarity of ethanolic solution.	-	Complies	-	-
Coloration of ethanolic solution.	haz	< 10	-	10
Heavy Metals	%	< 0,0010	-	0,0020
Chlorides (Cl-)	%	< 0,0100	-	0,0100
Residual solvents (none)	-	Guaranteed conformity	-	-
Sulphated ash/Residue on ignition	%	0,02	-	0,05
4-hydroxybenzoic acid	%	0,04	-	0,10
4-hydroxyisophthalic acid	%	0,04	-	0,05
Phenol	%	< 0,01	-	0,01
Total impurities	%	< 0,13	-	0,20
No other relat. subst.>0,05%	-	Complies	-	-

Batch released on : 12.16.2015

Person responsible for batch release: Isabelle COSTET

P.O L-FORESTIER



SALPH-PE/USP
2 - 10.13.2015