

Certificate of Analysis

Name of the product : Solacyl, water soluble powder

Product number : 94544640 Packaging : 1kg
Batch number : 108178 Date of analysis : 07-05-2018
Manufacturing date : 04-2018 CoA version : SC-LAB94544640.3.0
Expiry date : 04-2021 Destination : Hungary

DETERMINATIONS	SPECIFICATIONS	RESULTS
Characters	White to off-white flakes	White to off-white flakes
Appearance primary packaging	No deviations on sachets/bag and seal	No deviations on sachets/bag and seal
Identification Sodium salicylate	Positive	Positive
Clarity	As water	As water
Colour of solution	Not more intensely coloured than ref. sol. BY3	Not more intensely coloured than ref. sol. BY3
pH	6.0 – 8.0	7.1
Dissolving speed (min)	Not more than 10 minutes	Not more than 10 minutes
Microbiological quality	Complies to Ph. Eur. 5.1.4, Category 3A	*Not Performed
Loss on drying (%)	Not more than 0.5	0.2
Assay (%) Sodium salicylate	99.0 – 101.0	100.0
Weight (g)	1000 - 1075	1028

Stefan van Roosmalen



28 MEI 2018

* Not routinely tested but at least once a year.

Qualified Person

Conclusion : Conform specifications.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

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