
**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS**

GALDERMA
EST. 1981

QC Chemistry Department

ITEM DESCRIPTION: DIFFERIN ADAPALENE GEL 0.1% OTC 45G USA (X12)

ITEM NUMBER: 051887

EFFECTIVE DATE: 16-03-2022

GALDERMA LOT NUMBER: 362941

LIMS LOT NUMBER: B-20220307-00087

SAMPLE: S-220307-01138 Begin

| Test | Method | Limits | Results |
|---------------------------------|---------------------------|--|-----------|
| Description | 1.BD.05.MET.9000.R00 | A milky white, viscous gel, easily spread, no lumps. | Conforms |
| Note: Sample 2 | | | |
| pH | 1.BD.05.MET.9004.R01 A | 4.5 – 6.0. | 5.4 |
| Note: Sample 2 | | | |
| Particle Size | 1.BD.05.MET.9007.R03 | | |
| Particle Size < 20 µm | | Not less than 90% < 20µm | 100 % |
| Note: Sample 2 | | | |
| Particle Size < 50 µm | | Not less than 99% < 50µm | 100 % |
| Note: Sample 2 | | | |
| Viscosity | 1.BD.05.MET.9006.R02 E | 20 000 – 75 000 cPs | 40600 cPs |
| Note: Sample 2 | | | |
| Identification (by TLC) | 1.BD.05.MET.2025.R01 | | |
| Adapalene | | The principal spot from the sample preparation corresponds in Rf value to that of the standard. | Conforms |
| Note: Sample 2 | | | |
| Identification (by HPLC) | 1.BD.05.MET.2018.R05 | | |
| Adapalene | | The retention time of the major peak in the sample preparation essentially matches the retention time of the major peak in the working standard. | Conforms |
| Note: Sample 2 | | | |
| Assay | 1.BD.05.MET.2018.R05 | | |
| Adapalene | | 95.0% – 105.0% of Label claim. (Label claim | 99.5 % |

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SAMPLE: S-220307-01138 Begin

| Test | Method | Limits | Results |
|---------------------------------|----------------------|--|----------|
| | | :0.1% w/w) | |
| Note: Sample 2 | | | |
| Identification (by HPLC) | 1.BD.05.MET.2033.R06 | | |
| Methylparaben | | The retention time of the major peak in the sample preparation essentially matches the retention time of the major peak in the working standard. | Conforms |
| Note: Sample 2 | | | |
| Assay | 1.BD.05.MET.2033.R06 | | |
| Methylparaben | | 90.0% - 110.0% of Theoretical amount. (Theoretical amount: 0.1% w/w) | 97.6 % |
| Note: Sample 2 | | | |

This document was electronically approved by :

DENIS,Daniel, Chemist, Analytical Development Analyst

Date : 11-03-2022

**FINISHED PRODUCT
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EST. 1981

QC Microbiology Department

ITEM DESCRIPTION : DIFFERIN ADAPALENE GEL 0.1% OTC 45G USA (X12)

ITEM NUMBER : 051887

EFFECTIVE DATE : 16-03-2022

GALDERMA LOT NUMBER : 362941

LIMS LOT NUMBER : B-20220307-00087

SAMPLE : S-220307-01135 Composite

| Test | Method | Limits | Results |
|--|----------------------|--|------------|
| Microbial Limit Assay | 1.BD.05.MET.8000.R03 | | |
| Total Count | | Not more than 10 ² CFU/g | < 10 CFU/g |
| Note: sample 1 | | | |
| Absence of S. aureus, P. aeruginosa and other Objectionable microorganisms | | Absence of S. aureus, P.aeruginosa and other objectionable microorganisms / g | Absent |
| Note: sample 1 | | | |
| Microbial Examination of Non Sterile products: Tests for B. cepacia complex | 1.BD.05.MET.8003.R00 | | |
| Absence of Burkholderia cepacia complex Section 9.1 Parameter B | | Absence of Burkholderia cepacia complex / g | Absent |

This document was electronically approved by :

Suzie Robert, QC Microbiology Specialist

Date : 16-03-2022

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ITEM DESCRIPTION : DIFFERIN ADAPALENE GEL 0.1% OTC 45G USA (X12)

ITEM NUMBER : 051887

EFFECTIVE DATE : 16-03-2022

GALDERMA LOT NUMBER : 362941

LIMS LOT NUMBER : B-20220307-00087

SAMPLE : S-220307-01136 Composite

| Test | Method | Limits | Results |
|--|----------------------|--|------------|
| Microbial Limit Assay | 1.BD.05.MET.8000.R03 | | |
| Total Count | | Not more than 10^2 CFU/g | < 10 CFU/g |
| Note: sample 2 | | | |
| Absence of S. aureus, P. aeruginosa and other Objectionable microorganisms | | Absence of S. aureus, P.aeruginosa and other objectionable microorganisms / g | Absent |
| Note: sample 2 | | | |
| Microbial Examination of Non Sterile products: Tests for B. cepacia complex | 1.BD.05.MET.8003.R00 | | |
| Absence of Burkholderia cepacia complex Section 9.1 Parameter B | | Absence of Burkholderia cepacia complex / g | Absent |

This document was electronically approved by :

Suzie Robert, QC Microbiology Specialist

Date : 16-03-2022