**Text extracted from image7.png**

Certificate of Analysis

5824711N - BENYLIN DAY/NIGHT 16TABS GB

Lot ID: 1234VDREXT

Product Grade: ITA\_UK Manufacturing Date: 01-Jan-2025

Product Code: 5824711N Expiration Date: Dec-2026

Analysis Date: Dec-2024

complies with the specification: PR-007413, Rev 6/PR-008084, Rev 9

Test Method Specification Result

Colour and Appearance White, bioonvex tablet in

oblong form with bisecting

score on one side ~A7C ie

engraved on both aides of

the bisecting score

1478 esesee-1 Pase

1478 6868661 Paso

1478 1B086866-1 Pass

1478 980666-1 Pass

Paracetamol identification: Color reaction Positive

1478 986606-1 Pass

1478 0908061 Pass

1478 1980888-1 Pass

1478 1e88868-1 Pase

1478 esesee-1 Pase

Peeudoephedrine HC! Kdentifoation: TLC Positive

1478 6868681 Pase

1478 eee8ee-1 Pase

1478 e8686e-1 Pase

1478 13686868-1 Paso

1478 980666-1 Pass

IPC Appearance teat with 3 Puss Fall Smooth Cream

components

1154 Ba8deet-t Pass

HPLC ident Assay Purlty with 3 numeric, 4 Positive

numeric

1478 pee0806-1 Pass

1478 13988868-1 Pass

1478 es68ee-1 Pase

1478 es686e-1 Pase

IPC Appearance test with 3 Pase Fall Typical odor of 467650

components ENTRECHAT OPT A[RM00

01418)

1154 Bo0deet-t Pass

Secure Report ID: 602 CoA Setup: vt

(UMS Lot Num: 1488, Page 1 of 5 Print Date: 10-Feb-2025 10:39

COAID: 842.00 Dstabase: LabWare 8 SBX

**Text extracted from image8.png**

Certificate of Analysis

5824711N - BENYLIN DAY/NIGHT 16TABS GB

Lot ID: 1234VDREXT

Product Grade: ITA\_UK Manufacturing Date: 01-Jan-2025

Product Code: 5824711N Expiration Date: Dec-2026

Analysis Date: Dec-2024

complies with the specification: PR-007413, Rev 6/PR-008084, Rev 9

Test Method Specification Result

HPLC ident Assay Purlty with 3 numeri, 4 95.0- 108.0%

numeric

1478 e86868-1 100.0%

1478 ee68e8-1 100.0%

1478 es686e-1 100.0%

1478 6868661 100.0%

1478 6868661 100.0%

IPC Appearance test with 3 Puss Fall White

components

1156 9048s Pass

HPLC ident Assay Purlty with 3 numeri, 4

numeric

Paracetamol degredate (HPLC): 4-eminoph 0.05%

enol

1478 0808061 00%

1478 e86868-1 0.00%

Paracetamol degradate (HPLC): Other 01%

individual degradates

1478 686866-1 00%

1478 986866-1 0.0%

1478 eeeee6-1 00%

1478 10808081 00%

Paracetamol degradate (HPLC): Total =03%

egradatos

1478 esesee-1 02%

1478 6868661 02%

1478 1686868-1 02%

1478 980866-1 02%

HPLE with 1 Identification Pase-Fall comp, 4

umer

Active substance identification: Positive

Peeudoephedrine HC! identification

1478 6868681 Pase

1478 686868-1 Paso

1478 1686868-1 Paso

1478 980866-1 Pass

Secure Report ID: 602 CoA Setup: vt

(UMS Lot Num: 1488, Page 2 of 5 Print Date: 10-Feb-2025 10:39

COAID: 842.00 Dstabase: LabWare 8 SBX

**Text extracted from image9.png**

Certificate of Analysis

5824711N - BENYLIN DAY/NIGHT 16TABS GB

Lot ID: 1234VDREXT

Product Grade: ITA\_UK Manufacturing Date: 01-Jan-2025

Product Code: 5824711N Expiration Date: Dec-2026

Analysis Date: Dec-2024

complies with the specification: PR-007413, Rev 6/PR-008084, Rev 9

Test Method Specification Result

Pseudoephedrine HC! assay (HPLC) 95.0- 108.0%

1478 10908061 98.0%

1478 198086841 98.0%

1478 es686s-1 98.0%

1478 es686e-1 98.0%

1478 e868ee-1 98.0%

Pseudoephedrine HC! degradate (HPLC): 05%

Benzaldehyde

1478 eee806-1 02%

1478 10908081 02%

1478 1988868-1 02%

1478 es686e-1 02%

Peoudoephedtine HC! degradate (HPLC) 10%

“Total degradates

1478 1686866-1 00%

1478 9808661 0.0%

1478 eeeee6-1 00%

1478 19808081 00%

Peeudoephedtine HC! degradate (HPLC): 02%

Other individual degradaton

1478 16868661 0%

1478 6868661 0%

1478 136868661 0%

1478 oeeeee-1 0%

pH 4.500 - 5.500

1186 B304e41-1 50

Viscosity 2750.0 - 8250.0 mPas

1154 Ba8deett 8001 mPas

Dissolution stage 1 6 Vessels C-Value 80 Equal fo 4

mutt a

Density >= -bo000

1156 B90eeet-t 2.500

Dissolution stage 1 6 Vessels @-Value 80 Equal to 4

mutt a

Secure Report ID: 602 CoA Setup: vt

(UMS Lot Num: 1488, Page 3 of 5 Print Date: 10-Feb-2025 10:39

COAID: 842.00 Dstabase: LabWare 8 SBX

**Text extracted from image10.png**

Certificate of Analysis

5824711N - BENYLIN DAY/NIGHT 16TABS GB

Lot ID: 1234VDREXT

Product Grade: ITA\_UK Manufacturing Date: 01-Jan-2025

Product Code: 5824711N Expiration Date: Dec-2026

Analysis Date: Dec-2024

complies with the specification: PR-007413, Rev 6/PR-008084, Rev 9

Test Method Specification Result

Unif of Mass EP 2.9.5 Tablets (>=260 mg) -

SuppolP

‘Average 718.4000 - 744.6000 mg

Decision Equal to 4

Microbiology 2 components CFUlg, OOP 4

‘component A

‘DAY: Total Aerobic Microbial Count: TAMC <= 1000 CF Ula 10CFUg

DAY: Total Aerobie Microbial Count: TAMC <= 1000 CFUlg

DAY: Total Combined Yeasts and Moulds = 100 CFUlg 10CFUIg

Count: TYMC

DAY: Total Combined Yeasts and Moulds = 100CFUg

Count: TYG

DAY: Escherichia Colt Absence in 11g Absent

DAY: Escherichia Coli Absence in 11g

Microbiological Identification

‘Microbiological Identification PASS Pass

‘Microbiological Identification PASS.

Microblology with 2 Numer, 1 Absent Prose

ntand

'NIGHT:Total Arobio Microbial Count: TAMC. <= 1000 CFUlg 10cFUS

[NIGHT:Total Aerobic Microbial Count: TAMC. = 1000 CFUlg

NIGHT:Total Combined Yeasts and Moulds = 100CFUg 10cFUy

Count: TYG

[NIGHT:Total Combined Yeasts and Moulds = 100 CFUlg

Count: TYMC

NIGHT:Escherichia Coli Absence in 1.9 Absent

NIGHT:Escherichia Coli Abeence in 1.9

Check packaging

(Check packaging Compios Compiiee

(Check packaging Compios

(Check packaging Compiles

(Check packaging Complies

‘Secure Report ID: 602 CoA Setup: vt

(UMS Lot Num: 1488, Page 4 of 5 Print Date: 10-Feb-2025 10:39

COAID: 842.00 Dstabase: LabWare 8 SBX

**Text extracted from image11.png**

Certificate of Analysis

5824711N - BENYLIN DAY/NIGHT 16TABS GB

Lot ID: 1234VDREXT

Product Grade: ITA\_UK Manufacturing Date: 01-Jan-2025

Product Code: 5824711N Expiration Date: Deo-2026

Analysis Date: Dec-2024

complies with the specification: PR-007413, Rev 6/PR-008084, Rev 9

Test Method Specification Result

Deviation

Deviation There a no relevant Pass

deviation observed during

manufacturing process and

analytical testing.

Deviation There is no relevant

devition observed during

manufacturing process and

analytical teeting.

Deviation There is no relevant

deviation observed during

manufacturing process and

analytical testing.

Marketing Authorization Number : PL 18513/0108

Pharmaceutical Form: Tablets

Packaging Type Size: 1 blisters of 16

‘Actit{e}: Paracetamol DAY: 600 mg

Peeudoephedrine HCI DAY: 60 mg

Paracetamol NIGHT: 500 mg

Diphenydramine HCI NIGHT : 25 mg

Manufacturing Authorization Number: 2022\_238\_1\_2

EudraGMP Reference Number: 2021\_HPF\_FR\_140 NT P 2024

Microbial Monitoring Statement: Every 10th batch with a minimum of 1 batch per year

| hereby certify that the above Information is authentic and accurate. This batch of product has been

manufactured, Included packaging and quality control at the above mentioned site(s) in full compliance with the

GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authortzation of

‘he Importing country. The batch processing, packaging and analysis records were reviewed and found to be in

‘compliance with GMP.

lesued By: Mohsin Vijapure lesued Date: 10-Feb-2025

Admin

Dispositioned By: Christine Carretior Disposition Date: 07-Feb-2025

Release Date: 10-Feb-2025

Replaces Secure Report ID: 601 Dete: 10-Feb-2025 By: Mohsin Vjapure

Secure Report ID: 602 CoA Setup: vt

{UM Lot Num: 1488 Page 5 of 5 Print Date: 10-Feb-2025 10:39

CCOAID: 64200 Database: LabWere 8 SEX