



S.I.M.S.

Società Italiana Medicinali Scandicci

STABILIMENTI CHIMICO - FARMACEUTICI INDUSTRIALI

Società a responsabilità limitata - Capitale interamente versato € 2.750.000

Stabilimento e Amministrazione: Loc. Filarone - 50066 REGGELLO (FI)

Sede legale: Via Dante Da Castiglione, 8 - 50125 Firenze

Codice Fiscale/Partita I.V.A./VAT Number: IT 03076410483

Telefoni 055.863051 - 3 linee - Fax 055.863008 - C.C.I.A.A. Firenze 298960 - Iscr. Trib. Firenze N. 30820

OUR BANKERS: CARIGE Figline Valdarno - Branch IBAN code: IT88Z0617537851000000727280

CERTIFICATE OF ANALYSIS

Pag.

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REGGELLO

17.05.2012

Batch n° 145.061

ACEF SPA

VIA UMBRIA, 8/14

FIORENZUOLA D'ARDA

PC

Product: PROPRANOLOL HCL

Int.Code 0159-1 P

Quantity Kg.

25,00

Packing

FIBRE DRUMS

DESCRIPTION : White to off-white crystalline powder, odorless, bitter taste

SOLUBILITY : Soluble in water and in alcohol slightly soluble in
chloroform practically insoluble in ether.

STORAGE : Preserve in well-closed containers

The product complies with the guideline ICH/293/95 and the Annex
CPMP/QWP/450/03 for Residual solvents.

type of analysis

result/outcome

prescribed

BP-EP

IDENTIFICATION IR/Identificazione IR

conforming

Complies CRS

IDENTIFICATION CHLORIDE/Identif.Cloruri

positive

positive

IDENTIFICATION MP/Identificazione PF

163-165°C

163-166°C

ACIDITY OR ALCALINITY/Acidità o alcalinità

test pass

test pass

CLARITY OF SOLUTION/Chiarezza della soluz.

clear

clear

COLOUR OF SOLUTION/Colore della soluz.

<66

n.m.t.degree 6

HEAVY METALS/Metalli pesanti

<20 ppm

n.m.t. 20 ppm

LOSS ON DRYING/Perdita di peso

0.1%

n.m.t. 0.5%

RELATED SUBSTANCES (HPLC)/Comp.simili(HPLC)

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IMPURITY B (WS 377)/Impurezza B (WS 377)

not detected

n.m.t. 0.10%

EACH OTHER KNOWN IMPURITY/Ogni altra imp.c.

not detected

n.m.t. 0.10%

EACH UNKNOWN IMPURITY/Ogni impurezza scon.

<0.10%

n.m.t. 0.10%

TOTAL IMPURITIES/Impurezze Totali

0.023%

n.m.t. 0.40%

SULPHATED ASH/Ceneri solforiche

0.01%

n.m.t. 0.1%

ASSAY/Titolo

99.9%

99.0%-101.0%

USP