

1-Benzyl-3-gamma-dimethylamino-propoxy-1H-indazole hydrochloride

UQUIFA

Lote: 0020112

UQUIFA MÉXICO, S. A. DE C. V.

CERTIFICATE OF ANALYSIS

BENZYDAMINE HCl

LOT 1051118008.01

Benalgin

PM 345.9

C₁₉H₂₃N₃O · HCl

CAS: 132-69-4

EC No: 205-076-0

DESCRIPTION:	WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER VERY SOLUBLE IN WATER, FREELY SOLUBLE IN ETHANOL (96 %) AND IN CHLOROFORM; PRACTICALLY INSOLUBLE IN ETHER.
IDENTIFICATION A (IR):	POSITIVE	CONCORDANT WITH THE REFERENCE STANDARD
IDENTIFICATION B (CHLORIDES):	POSITIVE	POSITIVE
CLARITY AND COLOUR OF SOLUTION:	PASSES	CLEAR AND NOT MORE INTENSELY COLOURED THAN REFERENCE SOLUTION Y6.
PRIMARY AMINES:	COMPLIES	THE YELLOW COLOUR OBTAINED IS NOT MORE INTENSE THAN THAT OBTAINED BY TREATING 10 ML OF A 0.00005% W/V SOLUTION OF 2-AMINOBENZOIC ACID IN ETHANOL (96 %) IN THE SAME MANNER
pH (10%)	4.3	4.0 TO 5.5
RELATED SUBSTANCES	IMPURITY A: ND % IMPURITY B: 0.2 % IMPURITY C: 0.001 % OTHER SINGLE IMPURITY: 0.1 % TOTAL IMPURITIES: 0.4 %	NOT MORE THAN 0.2% NOT MORE THAN 0.5% NOT MORE THAN 0.1% NOT MORE THAN 0.1% NOT MORE THAN 1.0%
HEAVY METALS:	<10 ppm	NOT MORE THAN 10 ppm
LOSS ON DRYING:	0.03 %	NOT MORE THAN 0.5%
SULPHATED ASH:	0.02 %	NOT MORE THAN 0.1%
ASSAY TITRATION:	99.8 %	99.0% TO 101.0% DRIED BASIS
RESIDUAL SOLVENTS:	ETHANOL: 177 ppm TOLUENE: ND ppm	NOT MORE THAN 2000 ppm NOT MORE THAN 250 ppm

MONOGRAPH BP

MANUFACTURING DATE:
EXPIRY DATE:

DECEMBER 12, 2011

DECEMBER 12, 2016

ELABORATED

NAME: MAURICIO ORTEGA
TITLE: QUALITY CONTROL
DATE: DECEMBER 14, 2011

APPROVED:

NAME: JOSE LUIS PRATA
TITLE: QUALITY CONTROL HEAD
DATE: DECEMBER 14, 2011

Vo. Bo.

Q.I. Uvaldo Vázquez
RESPONSABLE SANITARIO