 GRUPO GRUNTHAL CHILE	BOLETIN DE ANALISIS		Código:	PO-MP-100376-01
			Fecha Emisión	may-14
		PREGABALINA	Fecha Expiración	may-19
		CONTROL DE CALIDAD	Reemplaza a	Formato General

Código	=	MP100376	Fecha de recepción	=	19-10-2015	Fecha Informe	=	26/10/2015	29-10-2015	2-11-2015
Lote N°	=	2PG0740815	Fecha de muestreo	=	19-10-2015	Fecha inicio	=	21/10/2015	24-10-2015	
Cantidad	=	250 KG	Muestreado por	=	V. Carmona	Fecha término	=	23/10/2015	24-10-2015	
Embalaje	=	Cuñetes Plásticos	Cant. Muestra	=	64.8 g	Analizado por	=	Jose H. Toledo	- ALVARADO NUNEZ	
			N° Bultos	=	10	Cuaderno	=	39	4	
			N° Bultos teóricos a muestrear	=	10	Folio N°	=	81-92-106	183	
			N° Bultos muestreados	=	10	Vence	=	07/2018		
						Reanalisis	=	44		

Proveedor = CHEMO S.A.
Procedimiento de muestreo PE-0402-0004-09

Bibliografia: = EA-MP-100376-02

PARAMETROS	RESULTADO	LIMITES
DESCRIPCION	Polvero cristalinico de color blanco	Polvero cristalinico de color blanco a casi blanco.
SOLUBILIDAD	Escasamente soluble en agua - Cumple liberamente soluble en acido clorhidrico diluido cumple	Escasamente soluble en agua. Libremente soluble en acido clorhidrico diluido
IDENTIFICACION	Ponativo, existe como la escoria - canchales POSITIVO - T2 corresponde al T2 del standard. 0.00%	A: IR B: HPLC No mas de 0.1%
RESIDUO DE IGNICION	0.2%	No mas de 0.5%
PERDIDA POR DESECACION	Menos de 0.002%	Maximo 0.002%
PUNTO DE FUSION	186°C	186 - 189°C
ROTACION ESPECIFICA	+11°	+10° a +12°
VALORACION	99.6% T.C % IC 99.8% em % bs base seca	98.0 - 101.0%, de C8H17NO2, calculado sobre base seca.
SUSTANCIAS RELACIONADAS	Cumple - 0.1% Cumple - 0.1%	No mas del 0.5%, impurezas individuales No mas del 1.0%, impurezas totales

OBSERVACIONES:

INGRESO POTENCIA A SAP:

EMBALAJE: Almacenar a temperatura ambiente

APPROBATO

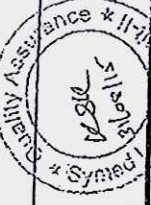
CALIFICACION

Juan Luis Arriagada
Q.F. Gerente Control de Calidad

SYMED LABS LIMITED (UNIT-II)

Plot No. 25/B, Phase - III, IDA, Jeedimetla, Hyderabad - 500 055, Telangana, INDIA. Tel: +91 40 23191337
URL : <http://www.symedlabs.com>, CIN : U24231TG1998PLC029961

Certificate of Analysis



Product	:	PREGABALIN	Reference	:	In - House
Batch No.	:	2PG 0740815	Quantity	:	250.0 Kg
Date of Manufacture	:	AUG- 2015	Date of Analysis	:	29/08/2015
Analytical Report No.	:	2PG 078/15	Re-test date	:	JULY- 2018
Storage conditions	:	Preserve in well closed, light resistant container. Store at 25°C, excursions permitted between 15° & 30°C			

S.No.	Test	Specifications	Results
1.	Description	A white to off white crystalline powder	A white crystalline powder
2.	Solubility	Sparingly soluble in water, Freely soluble in dilute HCl.	Complies
3.	Identification	a) IR: The Infra Red absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavelengths as that of a similar preparation of working standard. b) By HPLC: Retention time of the principal peak in the chromatogram obtained with sample solution should match with that of the principal peak in chromatogram obtained with standard solution.	Complies
*4.	Water Content	Not more than 0.50%w/w	0.05%w/w
*5.	Melting point	Should be between 187.0°C and 188.0°C	187.4°C
6.	Specific rotation	Should be between +10.0° and +12.0°	+10.358°
7.	Residue on Ignition	Not more than 0.10%w/w	0.04%w/w
8.	Heavy metals	Not more than 20 ppm	Less than 20ppm
9.	Related substances (by HPLC)	(S)(+)-Mandelic acid : Not more than 0.50% Any other Impurity : Not more than 0.50% Total Impurities : Not more than 1.0%	Not detected 0.05% 0.13%
10.	Assay on dried basis (by HPLC)	Should be between 98.0% and 101.0% w/w	100.0% w/w
*11.	Particle size	100% should be less than 500microns	282.5µm
*12.	Residual Solvents	Isopropyl alcohol : Not more than 5000 ppm	Not detected

The product conforms to the above Specifications.

*Additional test as per customer requirement.

Approved Signatory(QC):

Name : T.Brahma Reddy
Designation: Asst.Manager
Date

T. Brahma Reddy
21/08/2015

Authorised Signatory(QA):

Name : K.Sunil Kumar
Designation: Executive
Date

21/08/15