



TLC PHARMACHEM

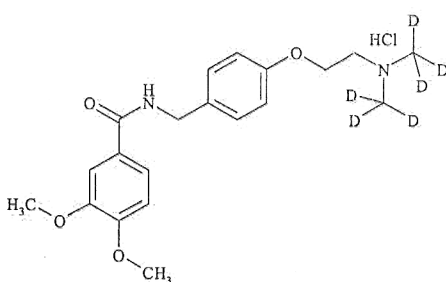
Certificate of Analysis

Certificate No.: 20140910B

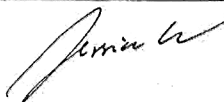
OFFICIAL QA COPY

Date: September 10, 2014

Retest date: September 2017

Compound Name:		Itopride-d6 HCl
CAS Number	122892-31-3	
Molecular Weight:	364.48 36.46	
Molecular Formula:	C20H20N2O4D6. HCl	
Source:	TLC PharmaChem., Inc.	
Source Lot No.:	1732-035A4	
Storage Conditions:	Store at 2-8 °C.	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 98.0%	98.7%
Isotopic Enrichment	Not less than 98.0%	99.6%
Recommendation:	Released. The compound contains 0.1% isopropanol according to its proton NMR.	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		07/22/2015
Approved by:	Quality Assurance		07/22/2015

Attachments: HPLC, MS and NMR spectra.

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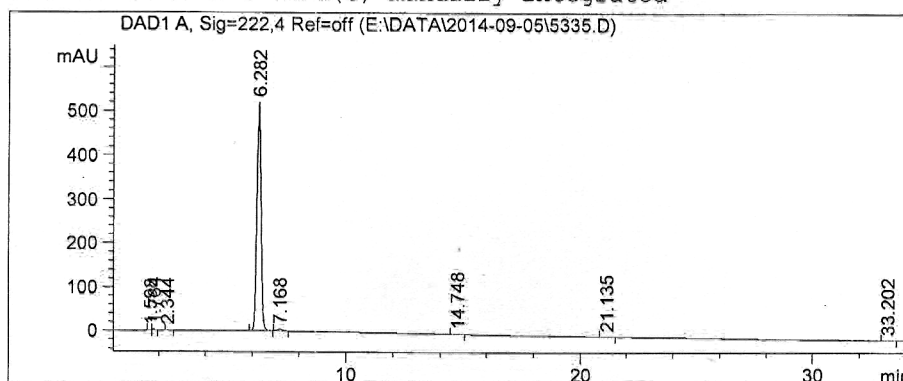
Acq. Operator : SYSTEM
Sample Operator : SYSTEM
Acq. Instrument : HPLC Location : Vial 81
Injection Date : 9/5/2014 4:43:47 PM Inj Volume : 1.200 µl

Acq. Method : C:\CHEM32\1\METHODS\DEF_LC.M
Last changed : 9/5/2014 5:17:00 PM by SYSTEM
(modified after loading)

Analysis Method : C:\CHEM32\1\METHODS\DEF_LC1.M
Last changed : 9/5/2014 5:22:33 PM by SYSTEM
(modified after loading)

Sample Info : ZORBAX Eclipse Plus-C18(4.6*100 mm,3.5 µm), F=1.0ml/min;T=30degree
CH3OH/10mmol/L CH3COONH4+0.03%TEA=45/55(0-5min);45/55-70/30(5-30min)

Additional Info : Peak(s) manually integrated



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Area Percent Report
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Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=222,4 Ref=off

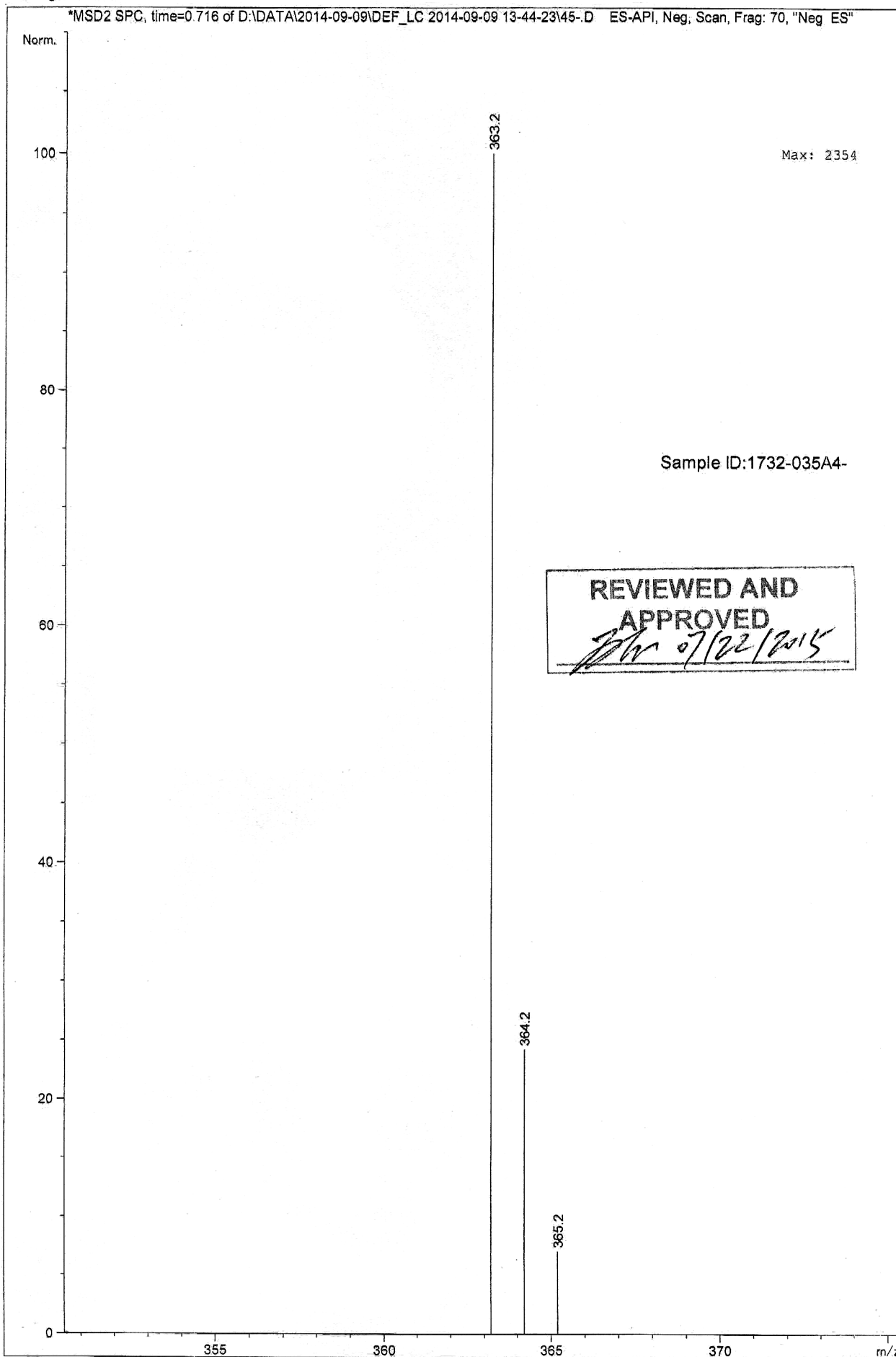
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	1.598	MF R	0.0803	3.66681	7.61413e-1	0.0562
2	1.764	FM R	0.0827	13.09771	2.63908	0.2009
3	2.344	FM R	0.1216	8.52551	1.16847	0.1308
4	6.282	MM R	0.2916	6436.27783	519.71460	98.7118
5	7.168	MM R	0.2272	42.37515	3.10806	0.6499
6	14.748	MM R	0.3003	4.53943	2.89435e-1	0.0696
7	21.135	MM R	0.2547	7.86475	5.14603e-1	0.1206
8	33.202	MM R	0.2617	3.92228	2.49800e-1	0.0602

Totals : 6520.26947 528.44546

REVIEWED AND
APPROVED

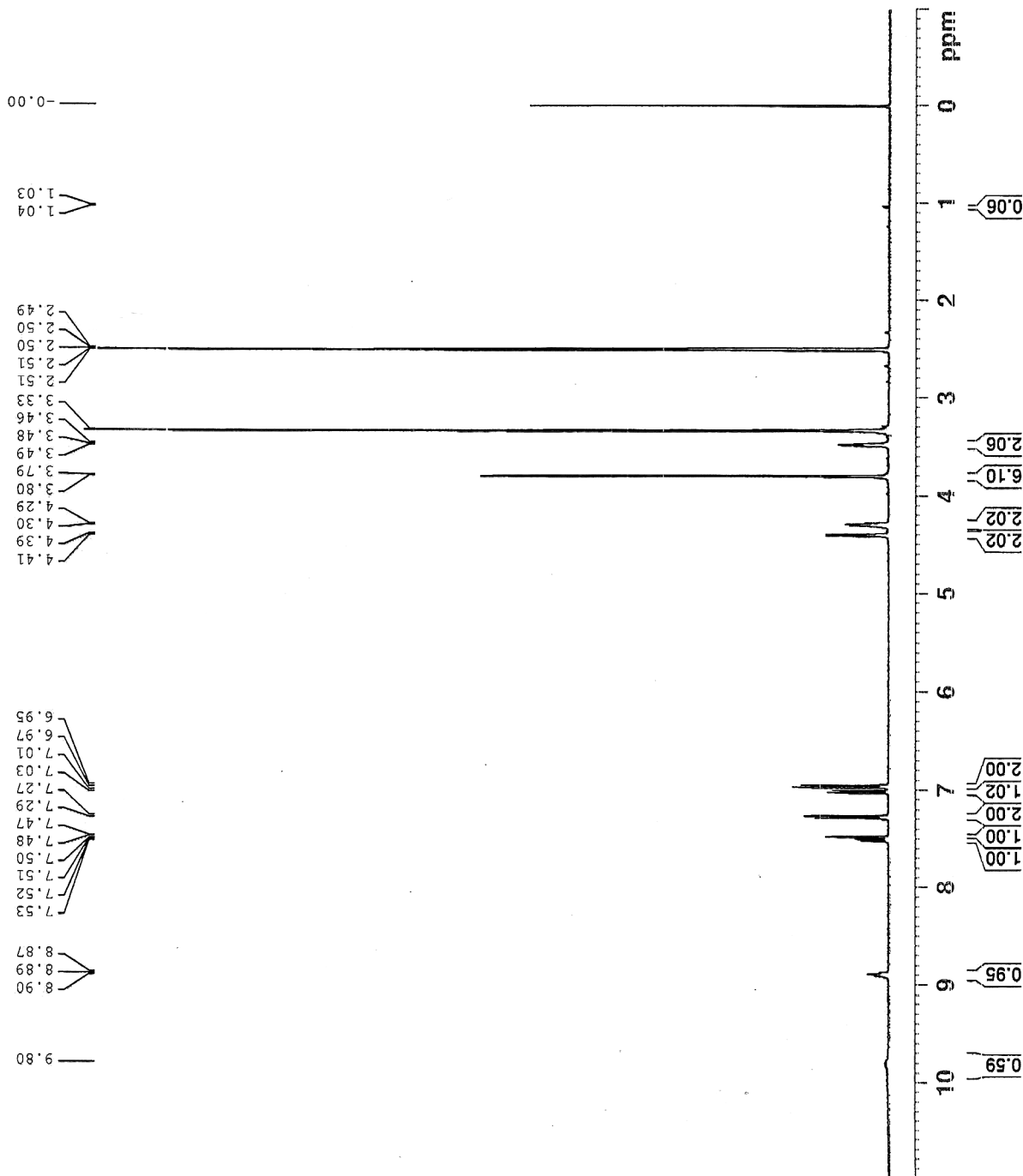
[Signature] 07/22/2015

MS Spectrum





1732-035A4 1H NMR in DMSO-d6



Current Data Parameters
NAME 2014-09-09
EXPNO 19
PROCNO 1

F2 - Acquisition Parameters
Date_ 20140909
Time 14.50
INSTRUM spect
PROBHD 5 mm PABBO BB/
PULPROG zg30
TD 65536
SOLVENT DMSO-d6
NS 16
DS 0
SWH 8802.817 Hz
FIDRES 0.134320 Hz
AQ 3.722448 sec
RG 115.63
DW 56.800 usec
DE 6.50 usec
TE 296.9 K
D1 1.00000000 sec
TD0 1

===== CHANNEL f1 =====
SF01 400.1332010 MHz
NUC1 1H
P1 10.00 usec
PLW1 16.00000000 W

F2 - Processing parameters
SI 32768
SF 400.1300023 MHz
WDW no
SSB 0
LB 0 Hz
GB 0
PC 1.00

REVIEWED AND
APPROVED

SP 07/22/2015