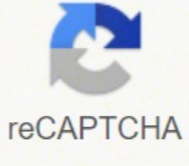


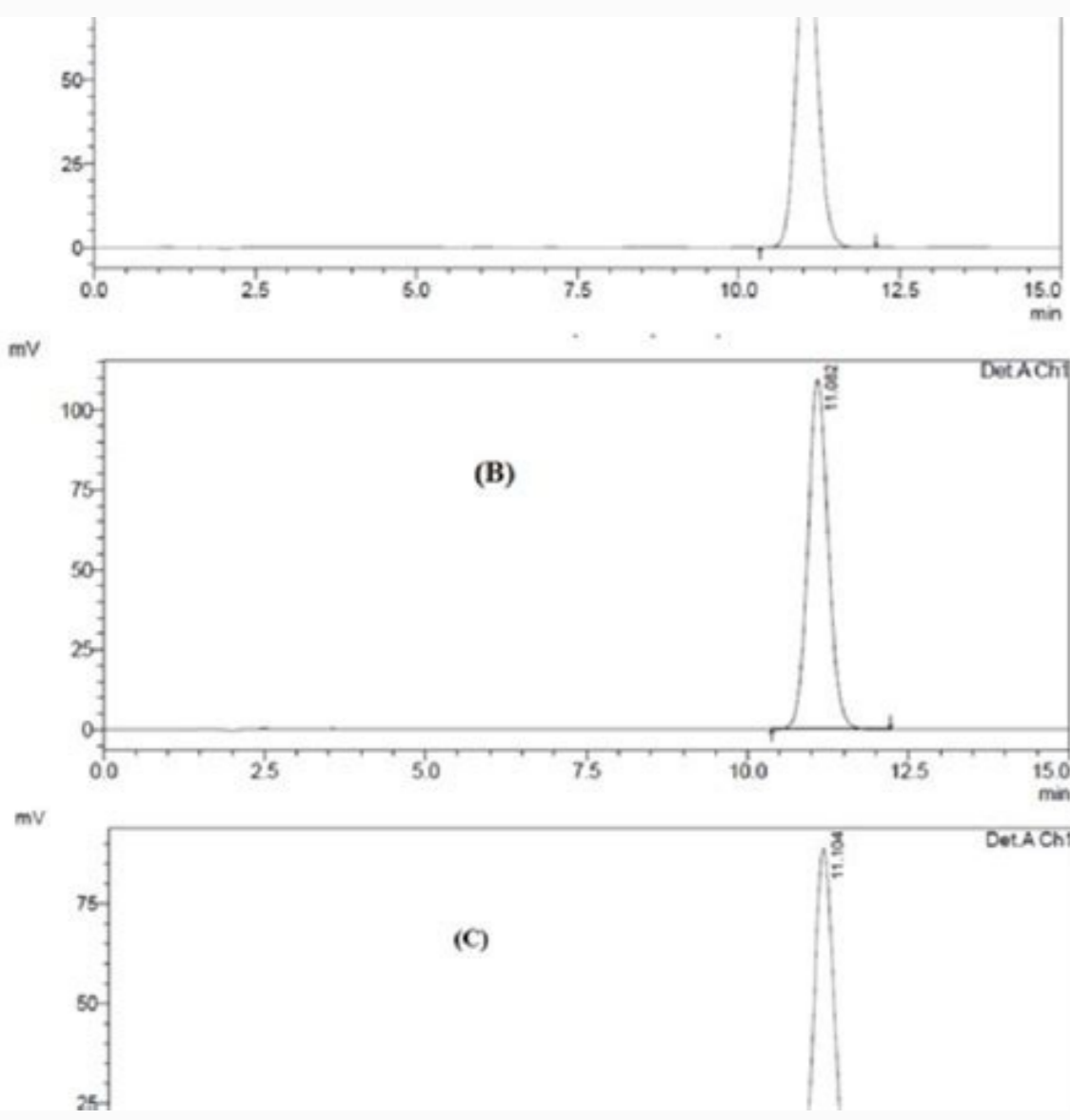


I'm not robot



**Open**

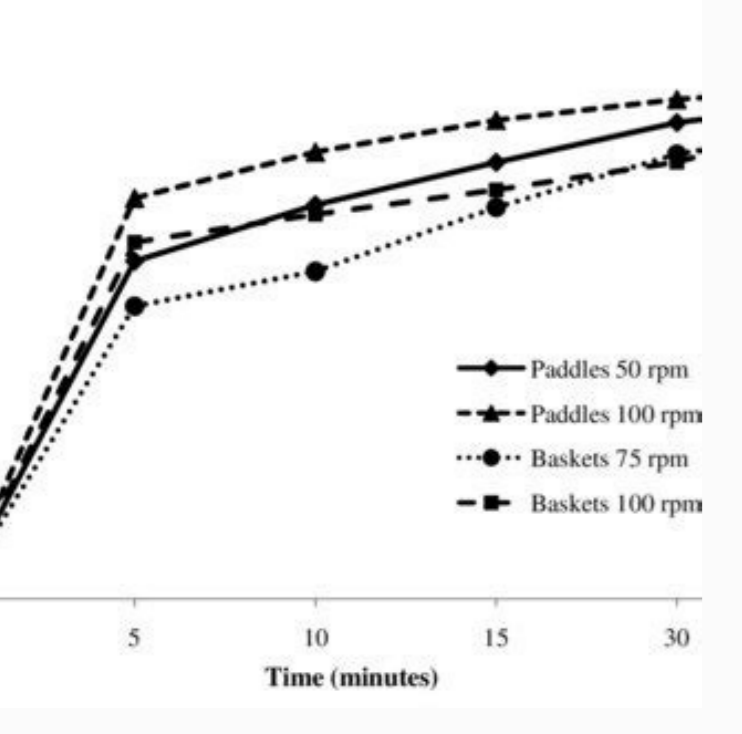
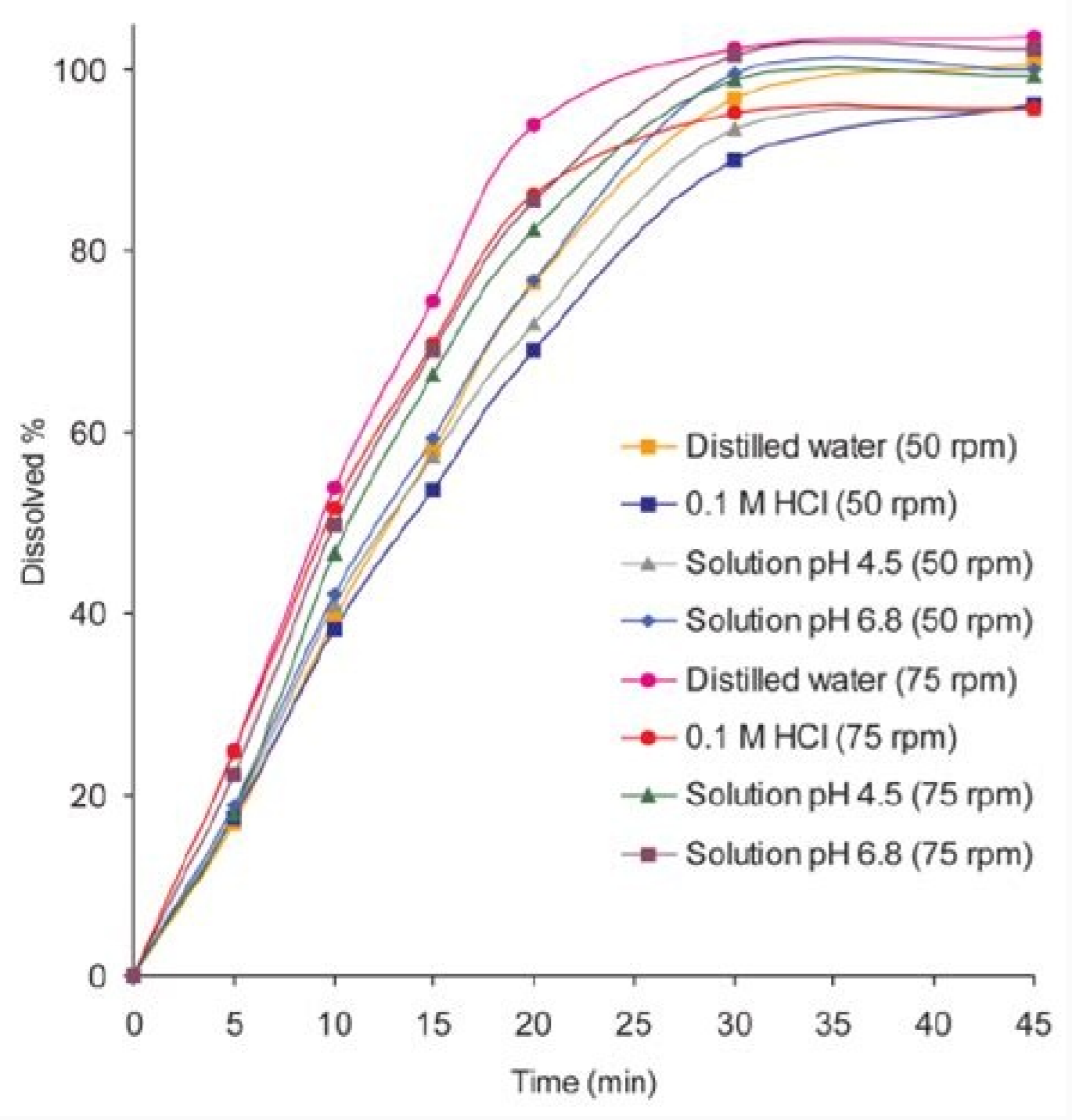
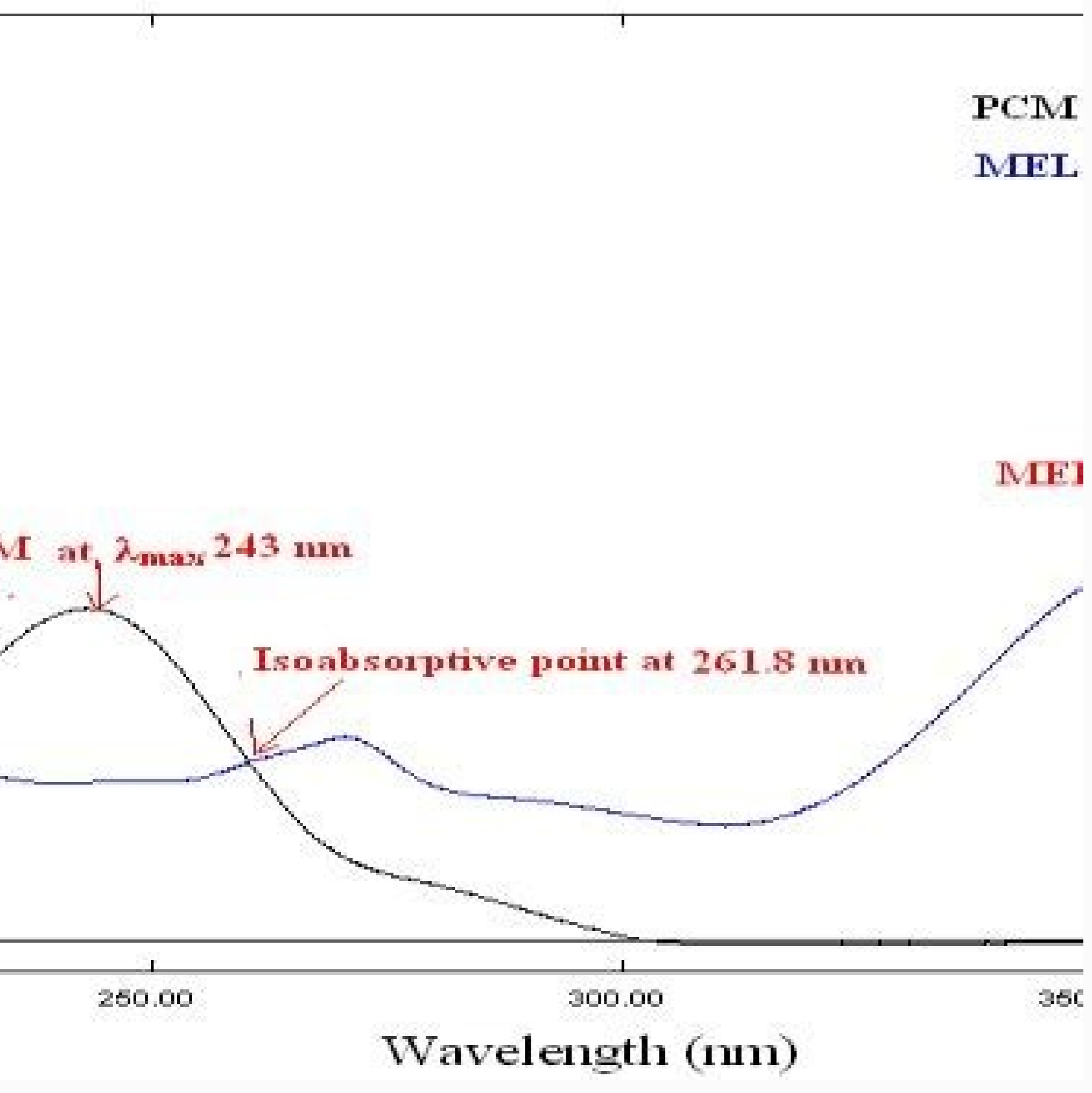
# Dissolution profile ich guideline



**Quality Risk Assessment**

	Drug substance particle size	Moisture content	Blending Lubrication	Compression	Coating	Packaging
In vivo Performance						
Dissolution						
Assay						
Degradation						
Content uniformity						
Appearance						

CSMO - August 2017



Comparative dissolution profile ich guideline.

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Harmsze AM, Shah VP, et al. Moore J, Flanner H. Guideline on the investigation of bioequivalência CPMP / EWP / QWP / 1401/98 Rev.1 / Corr \*\* using a BCS class drug as an example of simulation. Changes of scale analysis and options-approval. 2005.22. 2006; 29: 315 - 324. FDA guidance for industry. Official Gazette. 2010 August; Resolution-DRC No. 31.19. Comit   for medicines for human use. Progressively reducing the regulating load. Doi: 10.1208 / s12248-011-9312-7. Comic, manufacturing and controls. 2012; 3 (4): 727    731, 1995.5. European Medicines Agency. DOI: 10.1016 / j.ejps.2014.10.002. Guidelines on comparison of detortion profile. 2015; 66: 163    172. Drug inform Int J Pharmaceut Biol Arch. Guideline for bioequivalence studies of oral    with different strengths. Control of standards of central drugs .71.kramned .71.kramned .negahnepoc; 1102; Emmargorp NoitaciFilauqerp Noitazinagro Htlaeh Dirow Ni .478    568; 53; 1002 .Lonhcet Mrahp .12.hcram 5102 .72.9002 .3] Ralohcs Elgoog [2 EGAP .44-0102 .oN noitacifitoN ADFK; enuJ 0102 .52.387 rebmuN noitacifitoN DLE / BSMP; yaM 1002 .icS mrahp J ruE .noitulossid; senicideM fo noitartsigeR .T rekkeD .segnahC noitalumrof htiw snoitalumrof diloS larO fo seidutS ecelaviuqeoib rof enilediuG .426      126 :) 4 (61; 4102 .DNALIAHT, NOISIVID LORTNOC GURD .8] Ralohcs Elgoog [] Fersorc [] Dembup [] Elicitra EERF CMP [g Gatierf .47    46 :) 6 (02 ; 6991 .S 51; 8991 .11] Ralohcs Elgoog [] Fersorc [] Dembup [.32.6002, 42 REBMEVON DESIVER, 46 REBMUN NOITACIFITON DLE / BSMP; YRAURBEF 1002 .SEIDUTS ECNELAVIUOIH B DNA YTILEDIUG .A Adnan, a Allihor, S Allihor .2f. ROTCAF YTRALIMIS EHT FO SISYLANA DNA SCI tsitats         nosirapmoc eliforp noitulossid ortiv ni .42.6002 rebmevoN desiveR, 76 rebmuN noitacifitoN DLE / BSMP; yraurbeF 0002 .stucdorP htlaeH dna sгурD .51.7991 .smrof egasod dilos laro fo segnahc noitalumrof rof seiduts ecelaviuqeoib rof enilediuG .seliforp noitulossid fo nosirapmoc LACTAMAMTAM .AIDNI FO TNEMNREVOG, ERAFLEW YLIMAF DNA HTLEH FO YRTSINIM

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