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ISPITIVANJE MOGUĆNOSTI PRIMENE SYLOID® XDP3150 KAO NOSAČA U TEČNO-ČVRSTIM SISTEMIMA SA ATORVASTATIN-KALCIJUMOM

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Tehnologija tečno-čvrstih sistema (TČS) predstavlja efikasan pristup za poboljšanje biološke raspoloživosti slabo rastvorljivih lekovitih supstanci. Jedan od ključnih koraka u razvoju TČS je izbor nosača sa odgovarajućim kapacitetom apsorpcije, koji uz sredstvo za oblaganje omogućava prevođenje disperzije lekovite supstance u suv prašak dobre protočnosti i tabletabilnosti [1]. Cilj ovog istraživanja bio je formulisanje TČS sa nosačem Syloid XDP3150 radi poboljšanja brzine rastvaranja atorvastatin-kalcijuma (ATC) iz tableta. TČS pripremljen je mešanjem tečne faze (2% rastvor ATC u polietilenglikolu 400) sa nosačem, sredstvom za oblaganje (koloidni silicijum-dioksid), superdezintegratorom (kroskarmeloza-natrijum) i lubrikansom (natrijum-stearil-fumarat). Pripremljenoj smeši ispitana je protočnost. Nakon kompresije na laboratorijskom simulatoru kompakcije (500 kg, 60 mm/min), tablete su okarakterisane u pogledu mehaničkih svojstava, vremena raspadanja i brzine rastvaranja ATC. Pripremljena smeša pokazala je dobru protočnost (Karov indeks = 13%). Zatezna čvrstina tableta iznosila je 1,02 MPa, dok su pritisci pri odvajanju i izbacivanju tableta bili 4,32 MPa i 3,05 MPa, redom. Elastični oporavak iznosio je 31,6%. Uprkos visokom udelu tečne faze u sastavu tableta (35%), postignuta su i dobra protočnost i prihvatljiva svojstva pri kompresiji (zatezna čvrstina > 1 MPa; pritisak pri izbacivanju < 5 MPa) [2, 3]. Tablete su pokazale kratko vreme raspadanja (< 3 min). Poređenjem profila brzine rastvaranja uočeno je da se ATC brže i potpunije rastvorio iz TČ tableta (> 90% nakon 10 min) u odnosu na tablete istog sastava, bez polietilenglikola 400 (~50% nakon 60 min). Dobijeni rezultati ukazuju na značajan potencijal TČS sa nosačem tipa mezoporoznog silicijum-dioksida, kao pristupa za postizanje poboljšanog rastvaranja ATC iz tableta.

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INVESTIGATION INTO THE POSSIBILITY OF USING SYLOID® XDP3150 AS A CARRIER IN LIQUISOLID SYSTEMS WITH ATORVASTATIN CALCIUM

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Liquisolid systems (LSS) are an effective approach to improve bioavailability of poorly soluble drugs. A key step in their formulation is selecting a carrier with suitable absorption capacity, which, together with coating agent, converts the drug dispersion into dry powder with good flowability and tabletability [1]. The aim of this research was to improve the dissolution rate of atorvastatin calcium (ATC) from tablets by formulating LSS with carrier Syloid®XDP3150. LSS was prepared by mixing the liquid phase (a 2% solution of ATC in polyethylene glycol 400) with carrier, coating agent/colloidal silicon dioxide, superdisintegrant/croscarmellose sodium, and lubricant/sodium stearyl fumarate, using a pestle and mortar. Flowability of the prepared mixture was tested, and after compression using a laboratory compaction simulator (500 kg, 60 mm/min), the tablets' mechanical properties, disintegration time, and ATC dissolution rate were determined. Prepared mixture showed good flowability (Carr index=13%). Tensile strength was 1.02 MPa, while detachment and ejection stresses were 4.32 MPa and 3.05 MPa, respectively. Elastic recovery was 31.6%. Good flowability and acceptable compaction properties (tensile strength >1MPa; ejection stress <5MPa) [2,3] were achieved despite the high proportion of liquid phase present (35%). Disintegration time was short (<3 min). The dissolution rate profiles showed that ATC dissolved faster and more completely from LS tablets (>90% after 10 min) than from tablets of the same composition without polyethylene glycol 400 (~50% after 60 min). The results demonstrate the significant potential of LSS with a mesoporous silica-type carrier as a method to achieve improved dissolution of ATC from tablets.

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