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| ***Английский*** | ***Русский*** |
| Executive Summary**:**This pharmaceutical development summarizes the development of Carglumic acid tablets200mg, generic version of reference medicinal product, Carbaglu 200mg dispersible tablets(Orphan drug listed as reference medicinal product). Orphan Europe SARL Immeuble “LeWilson” 70 avenue du General de Gaulle F-92800 Puteaux, France is marketing authorizationholder and manufacturer for Carbaglu 200 mg dispersible tablet. The product was developedas immediate release dosage form in the form of dispersible tablets manufactured by directcompression process. Carglumic acid Tablet complies requirement of disintegration time ofless than 3 minutes and Fineness of dispersion test as per European Pharmacopeia, hence thisproduct can be proposed as carglumic acid dispersible tablet 200mg for Europe market. Qualityby Design (QbD) was used to develop generic Carglumic acid tablets 200mg that aretherapeutically equivalent to the reference medicinal product.Initially, the Quality Target Product Profile (QTPP) was defined based on the properties ofdrug substance, characterization of reference medicinal product, consideration of referencemedicinal product label and intended patient population. Identification of critical qualityattributes (CQAs) was based on the severity of harm to a patient (safety and efficacy) resultingfrom failure to meet that quality attribute of the drug product. Our investigation duringpharmaceutical development focused on those CQAs that could be impacted by a realisticchange to the drug product formulation or manufacturing process.Drug Release:Drug release is usually the rate limiting process for absorption of drug substance, Therefore,the dissolution of the reference medicinal product was thoroughly evaluated. Initially, thedissolution method recommended in the FDA dissolution methods database for this productwas utilized (750 mL of 0.05M Phosphate Buffer, pH 6.8 using USP apparatus 2 (paddle) at100 rpm).  |  |