|  |  |
| --- | --- |
| ***Английский*** | ***Русский*** |
| Executive Summary**:**  This pharmaceutical development summarizes the development of Carglumic acid tablets  200mg, generic version of reference medicinal product, Carbaglu 200mg dispersible tablets  (Orphan drug listed as reference medicinal product). Orphan Europe SARL Immeuble “Le  Wilson” 70 avenue du General de Gaulle F-92800 Puteaux, France is marketing authorization  holder and manufacturer for Carbaglu 200 mg dispersible tablet. The product was developed  as immediate release dosage form in the form of dispersible tablets manufactured by direct  compression process. Carglumic acid Tablet complies requirement of disintegration time of  less than 3 minutes and Fineness of dispersion test as per European Pharmacopeia, hence this  product can be proposed as carglumic acid dispersible tablet 200mg for Europe market. Quality  by Design (QbD) was used to develop generic Carglumic acid tablets 200mg that are  therapeutically equivalent to the reference medicinal product.  Initially, the Quality Target Product Profile (QTPP) was defined based on the properties of  drug substance, characterization of reference medicinal product, consideration of reference  medicinal product label and intended patient population. Identification of critical quality  attributes (CQAs) was based on the severity of harm to a patient (safety and efficacy) resulting  from failure to meet that quality attribute of the drug product. Our investigation during  pharmaceutical development focused on those CQAs that could be impacted by a realistic  change 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, the  dissolution method recommended in the FDA dissolution methods database for this product  was utilized (750 mL of 0.05M Phosphate Buffer, pH 6.8 using USP apparatus 2 (paddle) at  100 rpm). |  |